FLUKE®

Biomedical

SigmaPace 1000

External Pacemaker Analyzer

Operators Manual

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For application support or answers to technical questions, either email techservices@flukebiomedical.com or call 1-800- 648-7952 or 1-425-446-6945.

Claims

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Please note that only serialized products and their accessory items (i.e., products and items bearing a distinct serial number tag) are eligible for partial refund and/or credit. Nonserialized parts and accessory items (e.g., cables, carrying cases, auxiliary modules, etc.) are not eligible for return or refund. Only products returned within 90 days from the date of original purchase are eligible for refund/credit. In order to receive a partial refund/credit of a product purchase price on a serialized product, the product must not have been damaged by the customer or by the carrier chosen by the customer to return the goods, and the product must be returned complete (meaning with all manuals, cables, accessories, etc.) and in "as new" and resalable condition. Products not returned within 90 days of purchase, or products which are not in "as new" and resalable condition, are not eligible for credit return and will be returned to the customer. The Return Procedure (see below) must be followed to assure prompt refund/credit.

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Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-800-648-7952 or 1-425-446-6945.

Repair and calibration:

To find the nearest service center, go to www.flukebiomedical.com/service, or

In the U.S.A.:
Cleveland Calibration Lab
Tel: 1-800-850-4606
Email: globalcal@flukebiomedical.com

Everett Calibration Lab
Tel: 1-888-99-FLUKE (1-888-993-5853)
Email: service.status@fluke.com

In Europe, Middle East, and Africa:
Eindhoven Calibration Lab
Tel: +31-402-675300
Email: ServiceDesk@fluke.com

In Asia:
Everett Calibration Lab
Tel: +425-446-6945
Email: service.international@fluke.com

Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

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Manufacturing Location

The SigmaPace 1000 External Pacemaker Analyzer is manufactured in Everett, Washington by Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

Table of Contents

Chapter	Title	Page
1	**Introduction and Specifications**	**1-1**
	Introduction	1-3
	Compatible Pacemaker Types	1-3
	Incompatible Pacemaker Types	1-3
	General Safety Considerations	1-4
	Symbols	1-4
	Warnings and Cautions	1-4
	Power Supply	1-5
	Defibrillators and Transcutaneous Pacemakers	1-5
	Applications	1-6
	Features	1-6
	Unpacking and Inspection	1-7
	Instrument Familiarization	1-8
	Abbreviations	1-10
	General Specifications	1-12
	Instrument Specifications	1-12
	Transcutaneous Pacemaker Tests	1-13
	Transvenous Pacemaker Tests	1-17
	Accessories	1-28
2	**Setup, Operation, and Maintenance**	**2-1**
	Setting Up the Analyzer	2-3
	Connecting External Transcutaneous Pacemakers	2-3
	Connecting External Transvenous Pacemakers	2-4
	Load Test Cable Connector	2-4
	RS-232 Serial Port Connector	2-5
	High Level ECG Output Jack	2-5
	Ventilation	2-5
	Power Up Sequence	2-5
	Transcutaneous Pacemaker Testing	2-7
	Transvenous Pacemaker Testing	2-7
	Utility Functions	2-7
	Maintenance	2-8
	Avoiding Damage	2-8
	Cleaning	2-9

Service and Calibration 2-9
Packing Instructions 2-10
Shipping 2-10

3 Transcutaneous Pacemaker Testing 3-1
Test Options 3-3
Output 3-4
Demand Mode 3-5
Asynchronous Mode 3-5
Amplitude Sensitivity 3-5
Line Frequency / Noise Immunity 3-6
Refractory Period 3-6
Paced Refractory Period (PRP) 3-6
Sensed Refractory Period (SRP) 3-7
Long Term Test 3-8
Interactive Pacemaker / ECG Simulation 3-9
Simulated ECG Rate 3-9
Adjustable Threshold Level 3-9
Operational Modes 3-9
Continuous 3-9
Non-Capture 3-9
Non-Function 3-10
Setup and Testing 3-10
Output 3-12
Demand Mode Pacemaker's Interaction with ECG Signal 3-14
Continuous Mode Pacemaker's Interaction with ECG Signal 3-15
Demand Mode Pacemaker's Ability to Sense ECG Activity 3-17
Amplitude of ECG Signal for Demand Mode Pacemaker 3-20
Pacemaker's Ability to Filter Line Noise 3-23
Purpose of the ECG Simulation Test 3-26
Long Term Tests 3-27

4 Transvenous Pacemaker Testing 4-1
Test Options 4-3
Output 4-4
Demand Mode 4-4
Asynchronous Mode 4-4
Amplitude Sensitivity 4-5
Line Frequency / Noise Immunity 4-5
Refractory Period 4-5
Paced Refractory Period (PRP) 4-5
Sensed Refractory Period (SRP) 4-5
Interactive Pacemaker/ ECG Simulation 4-6
Simulated ECG Rate 4-6
PR Interval 4-6
Adjustable Threshold Level 4-6
Operational Modes 4-6
Continuous 4-6

Non-Capture 4-7
Non-Function 4-7
DC Leakage 4-7
Static Tests (Pacemaker Power OFF): 4-8
Dynamic Tests (Pacemaker Power ON):..... 4-9
Current Drain Test 4-9
Long Term Test 4-11
Setup and Testing 4-11
Output 4-13
Demand Mode and Dual-channel (AV) ECG Signal 4-16
Continuous Mode and Dual-channel (AV) ECG Signal 4-18
Demand Mode Pacemaker's Ability to Sense ECG Activity 4-20
Amplitude of ECG Signal for a Demand Mode Pacemaker..... 4-23
Pacemaker's Ability to Filter Line Noise..... 4-28
DC Leak Test..... 4-31
DC Load Test..... 4-34
ECG Simulation Test 4-36
Long Term Tests..... 4-38

5 Remote Operation 5-1

Introduction 5-3
Entering Remote Mode..... 5-3
Working in Remote Mode 5-3
Exiting Remote Mode..... 5-3
Command Syntax..... 5-4
Responses to Commands 5-4
Remote Mode Analyzer Setup Commands 5-4
Error Codes..... 5-5
Transcutaneous Pacemaker Remote Setup and Testing 5-6
Transvenous Pacemaker Remote Setup and Testing..... 5-13

List of Tables

Table	Title	Page
1-1.	Symbols	1-4
1-3.	Standard Accessories	1-28
1-4.	Pacemaker Disposable Electrode Adapters	1-28
1-5.	Serial Cables	1-29
1-6.	Compatible Power Supply	1-29
1-7.	Disposable Transcutaneous Pacemaker Adapters	1-29
1-8.	High-Level Output Cables	1-30
5-1.	SETMAKE Protocols by Manufacturer	5-7

List of Figures

Figure	Title	Page
1-1.	Analyzer Features and Controls	1-8
3-1.	Scheme for Testing Transcutaneous Pacemakers	3-4
3-2.	Paced Refractory Period	3-7
3-3.	Sensed Refractory Period	3-8
4-1.	Scheme for Testing Transvenous Pacemakers	4-3
4-2.	DC Leakage Testing	4-8
4-3.	Current Drain Test	4-10

Chapter 1
Introduction and Specifications

Contents **Page**

Introduction 1-3
Compatible Pacemaker Types 1-3
Incompatible Pacemaker Types 1-3
General Safety Considerations 1-4
Symbols 1-4
Warnings and Cautions 1-4
Power Supply 1-5
Defibrillators and Transcutaneous Pacemakers 1-5
Applications 1-6
Features 1-6
Unpacking and Inspection 1-7
Instrument Familiarization 1-8
Abbreviations 1-10
General Specifications 1-12
Instrument Specifications 1-12
Transcutaneous Pacemaker Tests 1-13
Transvenous Pacemaker Tests 1-17
Accessories 1-28

Introduction

The SigmaPace™ 1000 External Pacemaker Analyzer, hereafter referred to as the "Analyzer", is the latest in external pacemaker analyzer technology. This efficient, handheld Analyzer satisfies a wide range of external pacemaker testing; with a comprehensive range of test suites, measurement algorithms, and test loads.

Compatible Pacemaker Types

The Analyzer is designed to test temporary EXTERNAL pacemakers (pacers) only. These devices are commonly referred to by the following nomenclature:

- External transcutaneous pacemaker
- External transthoracic pacemaker
- External transvenous pacemaker
- External temporary pacemaker
- External AV sequential pacemaker
- Dual-Chamber temporary pacemaker
- Non-Invasive pacemaker

Incompatible Pacemaker Types

The Analyzer is not designed to test internal pacemakers. Additionally, it is not used to test any programmable implantable pacemakers, or any related implanted cardiovascular catheters or lead wires. These devices are commonly referred to using the following nomenclature:

- Internal pacemaker
- Implantable pacemaker
- Permanent pacemaker

Note

The Analyzer does not perform any clinical, diagnostic, therapeutic, or monitoring functions and is not for use directly with patients.

General Safety Considerations

This instrument and related documentation must be reviewed for familiarization with safety markings and instructions before you operate the instrument.

Symbols

Table 1-1 describes the symbols used on the instrument and/or in this document.

Table 1-1. Symbols

Symbol	Description
⚠	Important information; refer to manual.
⚠	Hazardous voltage
	Do not dispose of this product as unsorted municipal waste. Go to Fluke's website for recycling information.
	Conforms to relevant Australian EMC requirements
	Conforms to relevant Canadian and US standards
CE	Conforms to European Union directives
CAT I	IEC Measurement Category I – CAT I equipment designed to protect against transients in equipment on circuits not directly connected to MAINS. Under no circumstances should the terminals of the Analyzer be connected to any MAINS voltage.

Warnings and Cautions

A **Warning** identifies hazardous conditions and actions that could cause bodily harm or death.

A **Caution** identifies conditions and actions that could damage the Analyzer, the equipment under test, or cause permanent loss of data.

⚠⚠ Warning

To avoid possible electrical shock or personal injury, follow these guidelines:

- **Use this Analyzer only in the manner specified by the manufacturer, or the protection provided may be impaired.**
- **Read the Operators Manual before operating the Analyzer.**
- **Do not use the Analyzer if it operates abnormally.**
- **Do not use the Analyzer in wet locations, around explosive gases or dust.**
- **Use extreme caution when working with voltages above 30 volts.**
- **Use the proper terminals, functions and ranges for the test being performed.**
- **Do not connect the Analyzer to a patient or equipment connected to a patient. The Analyzer is intended for equipment evaluation only and should never be used in diagnostics, treatment or in any other capacity where the Analyzer would come in contact with a patient.**

Power Supply

Make sure the external battery charger / power supply is rated and configured for your voltage source, and compatible with the voltage and current ratings of the Analyzer. Use only the specified power supply included with this instrument. See Table 1-6.

Defibrillators and Transcutaneous Pacemakers

This instrument tests both external transcutaneous and transvenous pacemakers. In most cases, transcutaneous pacemakers are built into cardiac resuscitation equipment along with defibrillators. Defibrillators deliver high-voltage shocks to a patient in order to correct a life-threatening heart condition.

⚠ Caution

To avoid possible damage to the Analyzer, do not discharge defibrillator pulses into the instrument.

The dual-channel pacemaker input jacks are electrically protected to prevent damage if a defibrillator charge is applied. The instrument's internal buzzer activates to warn the user whenever a defibrillator pulse is sensed.

For transcutaneous pacemakers, both brand- and model-specific algorithms and testload ranges can be selected for particular device manufacturers.

Applications

The Analyzer can be used to test external pacemakers in the Coronary Care Unit (CCU) or Emergency Department (ED), to verify external pacemaker performance following factory repair / upgrade, or troubleshooting pacemaker operational problems.

The Analyzer is also a valuable clinical training and demonstration tool. In addition to measuring the pacemaker's basic output, amplitude sensitivity, and refractory capabilities, you can also present the interactive pacemaker operation using the standard ECG output with your bedside monitor, strip chart recorder or oscilloscope. The Analyzer realistically mimics a patient's cardiac response to the attached pacemaker including threshold / capture, basic asynchronous operation, and the four states of dual-channel transvenous pacemaker operation.

Testing is made easier with the Analyzer because you no longer need to switch test leads to conduct your desired atrial or ventricular channel test. All test functions, with the required ECG waveforms, are instantly available to the user via internal relay routing.

Features

- Tests both external transcutaneous and transvenous pacemakers.
- Large 21-character x 8-line alphanumeric LCD readout shows more information than other external pacemaker Analyzers.
- Full range of selectable measurement algorithms and test loads for external pacemakers.

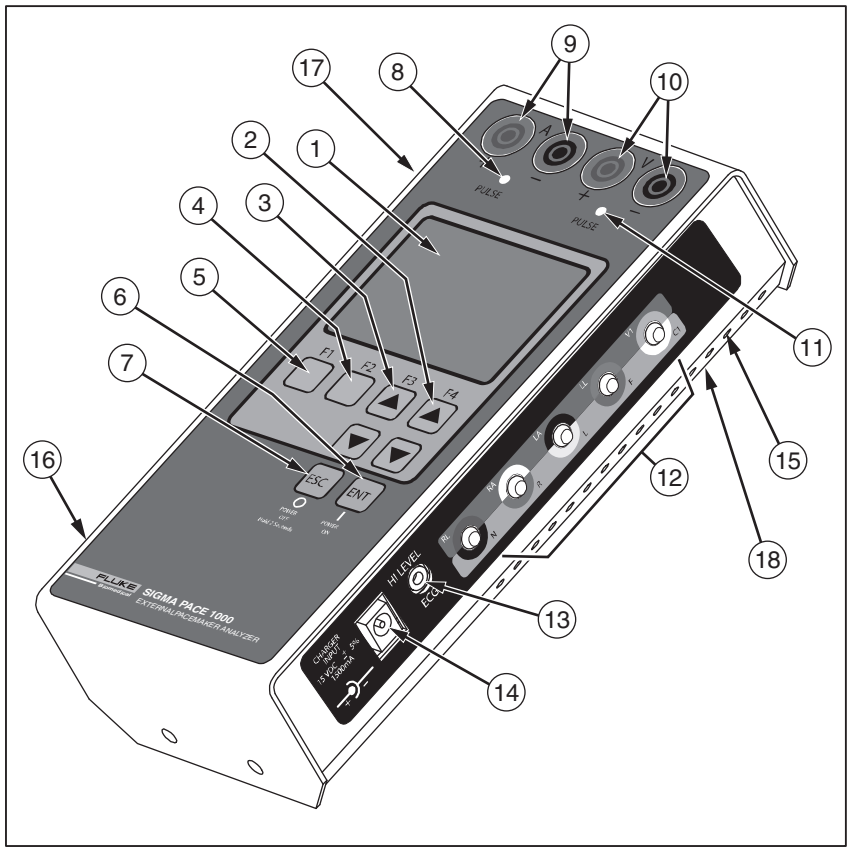
- Dual-channel signal acquisition for capturing synchronous transvenous AV-Sequential pacemaker pulse output data.
- Interactive pacemaker and ECG simulation with 5 Lead output.
- A Sleep mode conserves the charge of the internal lithium-ion battery when not in use. Sleep mode is disabled when the external power supply is plugged into a suitable voltage source.
- A "HOLD" function to "freeze" readings on the LCD.
- Test features for battery load current and dc leakage measurement.

Unpacking and Inspection

When unpacking the Analyzer, check for damage during shipment. If the Analyzer has been damaged, call your Fluke Biomedical Service Center immediately. If you must return the Analyzer to Fluke for service, follow the procedure given under "Service and Calibration."

Instrument Familiarization

The Analyzer's features and controls are shown in Figure 1-1 and described in Table 1-2.



eyr056.eps

Figure 1-1. Analyzer Features and Controls

Table 1-2. Analyzer Features and Controls

Number	Description
Top Panel	
1	LCD Readout (8 Lines X 21 Characters)
2	F4 / UP and DOWN Arrow Keys
3	F3 / UP and DOWN Arrow Keys
4	F2 Key
5	F1 Key
6	ENTER and POWER ON Key
7	ESCAPE and POWER OFF Key
8	Atrial Channel Sense Indicator (Yellow LED)
9	Atrial Channel Pacemaker Input Jacks (4 mm) Red: Positive Black: Negative
10	Ventricular Channel Pacemaker Input Jacks (4 mm) Red: Positive Black: Negative (Transvenous and Transcutaneous)
Right Side Panel	
11	Ventricular Channel Sense Indicator (Yellow LED)
12	Low Level ECG Output (Disposable Snap Compatible)
13	High Level ECG Output (Subminiature Phone Jack)
14	Charger / dc Power Supply Input Jack
15	Ventilation Slots
Left Side Panel	
16	Load Current (Phantom Battery) Input Connector
17	RS-232 Serial Port
Bottom Panel	
18	RESET Button

Abbreviations

The following list includes abbreviations used in this document.

A	ampere
ANSI	American National Standards Institute
AAMI	Association for the Advancement of Medical Instrumentation
BLU	blue (color)
BPM	beats per minute
dB	decibel
°C	degrees Celsius (centigrade)
CQM	Contact Quality Monitor
DMM	digital multimeter
DUT	device under test
EEPROM	electrically erasable PROM
ECG	electrocardiograph or electrocardiogram
ESU	Electrosurgery Unit
EUT	equipment under test
°F	degrees Fahrenheit
GRA	gray (color)
GRN	green (color)
Hz	hertz
in	inch
J	Joules
k	kilo (10^3)
kg	kilogram
kHz	kilohertz

kΩ	kilohm
lb	pound
LED	light-emitting diode
LCD	liquid crystal display
M	meg(a) (10^6)
MHz	megahertz
MΩ	megohm
m	meter
m	milli (10^{-3})
mA	milliampere
mm	millimeter
mV	millivolt
p-p	peak-to-peak
REM	Return Electrode Monitor
s	second
YEL	yellow (color)
µ	micro (10^{-6})
µA	microampere
µV	microvolt
Ω	ohm

General Specifications

Listed product specifications are subject to change.

Temperature
- Operating ..... 18 - 40 °C
- Storage ..... 0 - 50 °C

Relative Humidity, Operating ..... 90 % max (non-condensing)

Altitude ..... 2000 m

Serial Port
- Connector Type ..... DB-9 (Male)
- Baud Rates ..... 2400, 9600, and 19200

Service Manual 2243314

Power Requirement
- External Battery Charger / Power Supply
  - Input ..... 90-264 V, 50/60 Hz
  - Output ..... 15 V +/-5 %, 1500mA 100 to 240 V ac 50 / 60 Hz operation
- Auto power off / sleep mode

Sleep Modes
- Reset ..... Analyzer reset button accessed via bottom panel. Sleep mode conditions.

Physical
- Size ..... 8” X 4” X 2” (approx.) (203 mm X 101 mm X 50 mm)
- Weight ..... 2 lb (0.90 kg) approximate

Instrument Specifications

Modes of Operation
- Manual
- Remote (via standard RS-232 serial port)

User Interface
- Display
  - LCD Readout ..... 21 characters X 8 lines Brightness / viewing angle adjustment
- Pushbuttons
  - Eight keys ..... F-1, F-2, F-3 (UP Arrow), F-4 (UP Arrow), 2 Down Arrows, ESCAPE, and ENTER

Transcutaneous Pacemaker Tests

Output Pulse Measurement

Test Type ..... Quantitative

Measurement Ranges

Output ..... 4.0 mA to 9.99 mA
10.0 mA to 99.9 mA
100 mA to 250 mA

Accuracy ..... ±2 % of reading or ±50 µA (whichever is greater)

Rate ..... 5.0 PPM to 99.9 PPM
100 PPM to 300 PPM

Accuracy ..... ±0.5 % of reading or 0.3 PPM (whichever is greater)

Width ..... 1.00 mS to 9.99 mS
10.0 mS to 99.9 mS

Accuracy ..... ±0.5 % of reading or 14 µS (whichever is greater)

Energy ..... 1µJ to 999 µJ
1 mJ to 999 mJ
1.00 J to 1.99 J

Accuracy ..... ±5 % of reading / computation

Demand Mode Test

Test Type ..... Qualitative

Physiological Simulation

Selection ..... Normal Sinus Rhythm (NSR) generates the complete P-QRS-T complex.

Amplitude ..... (V_{peak}): 1.0 mV Lead I.

Mode of Operation

Underdrive ..... NSR @ 85 % of measured pulse interval / rate

Overdrive ..... NSR @ 115 % of measured pulse interval / rate

Auxiliary Control ..... The under / overdrive NSR simulations can also be independently adjusted in 1 BPM increments.

Auxiliary Rate Range

Underdrive (minimum).....10 BPM

Overdrive (maximum).....300 BPM

Active Outputs

Five lead ECG

Selected Ventricular Channel Test Load

High Level ECG Jack

This waveform is present on these three outputs.

Pacemaker Compatibility

Compatible Pulse Rates.....30 to 200 PPM

Intended Type .....External Transcutaneous VVI (Ventricular Only Pace and Sense)

Asynchronous Mode Test

Test Type.....Qualitative

Physiological Simulation Selection

Selection.....Normal Sinus Rhythm (NSR) generates the complete P-QRS-T complex.

Amplitude (V_{peak}).....1.0 mV Lead I

Rate (Interval)

Underdrive.....NSR @ 85 % of measured pulse interval / rate

Overdrive.....NSR @ 115 % of measured pulse interval / rate

Auxiliary Control .....The under / overdrive NSR simulations can be independently adjusted in 1 BPM increments.

Auxiliary Rate Range

Underdrive (minimum).....10 BPM

Overdrive (maximum).....300 BPM

Active Outputs

Five lead ECG

Selected Ventricular Channel Test Load

This waveform is present on both outputs.

Pacemaker Compatibility

Compatible Pulse Rates.....30 to 200 PPM

Intended Type

External Transcutaneous

VOO (Asynchronous Ventricular Only Pace)

Amplitude Sensitivity Test

Physiological Simulation

Selection ..... +R-Wave, -S-Wave, and + T-Wave

Rate (Interval) ..... Default: 120 BPM (500 mS)

Available Test Load

Selection(s) ..... (30) 50 Ω to 1550 Ω in 50 Ω steps

Waveform Selections ..... Square (SQU)
Triangle (TRI)
Haversine (HSN)
SSQ

Amplitude

Range ..... 0.05 mV_{peak} (50 V_{peak}) to 5.0 mV_{peak}

Accuracy ..... ±5 % of setting

Resolution (Step Size) ..... 0.05 mV steps from 0.05 mV_{peak} to 0. 95 mV_{peak} 0.50 mV steps from 1.0 mV_{peak} to 5.0 mV_{peak}

Width

Range ..... 0.15 mS to 300 mS

Accuracy ..... ±5 % of setting

Selection Count 50

Resolution (Step Size) ..... 0.05 mS steps from 0.15 mS to 0.95 mS
1.0 mS steps from 1.0 mS to 19.0 mS
5.0 mS steps from 20 mS to 95.0 mS
25 mS steps from 100 mS to 300 mS

Active Outputs

Five lead ECG

Selected Ventricular Channel Test Load

High Level ECG Jack

This waveform is present on these three outputs.

Pacemaker Compatibility

Compatible Pulse Rates ..... 30 to 200 PPM (Minimum)

Intended Pacemaker Type ..... VVI (Ventricular Pace and Sense Only)

Noise Immunity Test

Waveform ..... Sine Wave

Frequency ..... 50 and 60 Hz

Accuracy ..... 0.5 Hz

Active Outputs

Selected Ventricular Channel Test load

Five lead ECG

Testload Amplitude Output

Ventricular Channel

Range.....0.00 (OFF) to 10.0 $mV_{peak\text{-}to\text{-}peak}$

Accuracy.....±5 % of setting

Resolution (Step Size).....0.50 $mV_{peak\text{-}to\text{-}peak}$ steps

Pacer Load Range .....(30) 50 Ω to 1550 Ω 1 %

Five Lead ECG Output

Range.....0.00 (OFF) to 10.0 $mV_{peak\text{-}to\text{-}peak}$

Accuracy.....±5 % of setting

Resolution (Step Size).....0.50 mV steps

Calibration Reference.....Lead I (RA to LA)

Paced Refractory Period Test (PRP)

Range.....20 mS to 500 mS

Accuracy.....5 % of reading or 1 mS whichever is greater

Physiological Simulation

Selection.....Triangle (TRI) Wave

Pulse Width .....40 mS

Rate.....Single pulse: Interactive with applied pacemaker pulse activity in the demand mode of operation.

Amplitude .....1.0 mV_{peak} Lead I

Active Outputs .....Five Lead ECG and selected ventricular channel test load This waveform is present on both outputs.

Pacemaker Compatibility

Compatible Pulse Rates.....30 to 200 BPM

Intended Pacemaker Type .....VVI (Ventricular Pace and Sense Only)

Sensed Refractory Period Test (SRP)

Range.....15 mS to 500 mS

Accuracy.....±5 % of reading or ±1 mS, whichever is greater

Physiological Simulation

Selection.....Triangle (TRI) Wave

Pulse Width..... 40 mS

Rate ..... Double pulse: interactive with applied pacemaker pulse activity in the demand mode of operation.

Amplitude ..... 1.0 m V_{peak} Lead I

Active Outputs ..... Five Lead ECG and selected ventricular channel test load. This waveform is present on both outputs.

Pacemaker Compatibility

Compatible Pulse Rates ..... 30 to 200 BPM

Intended Pacemaker Type..... VVI (Ventricular Pace and Sense Only)

Transvenous Pacemaker Tests

Output Pulse Measurement

Test Type ..... Quantitative

Display Formats

Single..... Atrial or Ventricular only

Dual ..... Atrial and ventricular Channels

Measurement Ranges

Current..... 0.05 mA to .999 mA* (Single Channel Only)
1.00 mA to 9.99 mA
10.0 mA to 30.0 mA

Accuracy..... 2 % of reading or ±50 μA (whichever is greater)

Polarity Indicator..... + or -

Rate ..... 10 PPM to 99.9 PPM
100 PPM to 999 PPM

Accuracy..... 0.5 % or 0.3 PPM (whichever is greater)

Width..... 0.02 mS to .999 mS
1.00 mS to 9.99 mS
10.0 mS to 99.99 mS

Accuracy..... 0.5 % or ±14 μS (whichever is greater)

Resolution..... ±1 LSD or ±4 μS (whichever is greater)

Voltage ..... 0.050 V_{peak} to .999 V_{peak}
1.00 V_{peak} to 9.99 V_{peak}
10.0 V_{peak} to 30.0 V_{peak}

Accuracy.....2 % of reading or 0.05 V_{peak} (whichever is greater)

Polarity Indicator.....+ or -

Energy .....1 nJ to 999 nJ
1 μJ to 999 μJ – add "J" range

Accuracy.....5 % of reading / computation

Displayed Data

Single: Amplitude - Current

Amplitude .....Volts

Rate

Width

Energy

Dual: Atrial and Ventricular

Amplitude .....Current

Rate

Width

AV Interval

AV Interval (Delay Time)

Test Type.....Quantitative

Measurement Ranges

10.0 mS to 99.9 mS

100 mS to 999 mS

Start / Stop Points

Start.....Leading edge of atrial pacemaker pulse

Stop .....Leading edge of ventricular pacemaker pulse

Accuracy.....1 % of reading / computation

Demand Mode Test

Test Type.....Qualitative

Channels

Single .....Atrial or Ventricular Only

Dual .....A+V

Simulation

Waveform ..... SSQ

Atrial Channel ..... Simulated P-wave

Width..... 30 mS

Amplitude..... 2.0 mV_{peak}

Ventricular Channel ..... Simulated R-wave

Width..... 40 mS

Amplitude..... 2.5 mV_{peak}

PR Interval ..... 90 mS

Interactive Simulated Rates

Default Settings

Underdrive ..... NSR @ 85 % of measured pulse interval / rate

Overdrive ..... NSR @ 115 % of measured pulse interval / rate

Manual Control ..... The under / overdrive NSR simulations can also be independently adjusted in 1 BPM increments.

Manual Rate Limits

Underdrive (minimum) ..... 10 BPM

Overdrive (maximum) ..... 300 BPM

Active Outputs (Synchronous)

Selected Ventricular Channel Test Load

Selected Atrial Channel Test Load

Pacemaker Compatibility

Pulse Rate Range..... 30 to 200 PPM

Intended Pacemaker Types

VVI (Ventricular Channel Only: Pace and Sense)

AAI (Atrial Channel Only: Pace and Sense)

DDD (Both Channels: Pace and Sense)

Asynchronous Mode Test

Test Type ..... Qualitative

Channels

Single..... Atrial or Ventricular Only

Dual ..... A+V

Amplitude Sensitivity Test

Test Type.....Qualitative

Channels

Single Channel Operation Only (Atrial or Ventricular)

Atrial Channel

Test Type.....Quantitative

Physiological Simulation

Selection.....+P-Wave

Rate.....30 to 120 BPM, Waveform delayed by 80 % of the pulse-to-pulse interval or 400 mS (whichever is shorter).

Active Outputs

Atrial Channel (4mm Banana Jacks) Only Test Load(s)

Available Selection(s).....(3) 200 Ω, 500 Ω, and 1000 Ω ±1 %

Default Setting.....500 Ω

Waveform Selections .....Square (SQU)
Triangle (TRI)
Haversine (HSN)
Sine Square (SSQ)
Asymmetrical Triangle (ISO)
(Fixed Width 2 mS rise time / 13 mS fall time)

Default Setting .....SSQ

Amplitude

Pacer Load Selection .....500 Ω (default)

Range.....0.05 mV_{peak} (50 V_{peak}) to 50.0 mV_{peak}

Accuracy.....±5 % of setting

Resolution (Step Size).....0.05 mV_{peak} steps from 0.05 mV_{peak} to 0.95 mV_{peak}
0.50 mV_{peak} steps from 1.0 mV_{peak} to 50.0 mV_{peak}

Pacer Load Selection .....200 Ω

Range.....0.05 mV_{peak} (50 V_{peak}) to 20.0 mV_{peak}

Accuracy.....±5 % of setting

Resolution (Step Size).....0.05 mV_{peak} steps from 0.05 mV_{peak} to 0.95 mV_{peak}
0.50 mV_{peak} steps from 1.0 mV_{peak} to 20.0 mV_{peak}

Pacer Load Selection..... 1000 Ω
Range ..... 0.05 mV_{peak} (50 V_{peak}) to 100 $mV_{peak-to-peak}$
Accuracy ..... ±5 % of setting
Resolution (Step Size)..... 0.05 mV_{peak} steps from 0.05 mV_{peak} to 0.95 mV_{peak}
0.50 mV_{peak} steps from 1.0 mV_{peak} to 49.5 mV_{peak}
05.0 mV_{peak} steps from 50 mV_{peak} to 100 mV_{peak}

Default Setting
Amplitude..... 2.0 mV_{peak}

Width
Range ..... 0.15 mS to 95.0 mS
Accuracy ..... ±5 % of setting
Selection Count 50
Resolution (Step Size)..... 0.05 mS steps from 0.15 mS to 0.95 mS
1.0 mS steps from 1.0 mS to 19.0 mS
5.0 mS steps from 20 mS to 95.0 mS

Intended Pacemaker Types
AAI (Atrial Pace and Sense Only)
Compatible Pulse Rates ..... 30 to 200 PPM

Ventricular Channel

Physiological Simulation
Selection ..... +R-Wave, -S-Wave, and + T-Wave
Rate ..... 30 to 120 BPM, Delayed from the ventricular demand pacemaker pulse by 80 % of the pulse-to-pulse interval or 400 mS (whichever is shorter).

Active Outputs ..... Selected ventricular test load (4 mm Banana Jacks) only.

Waveform Selections
Square (SQU)
Triangle (TRI)
Haversine (HSN)
Sine Square (SSQ)
Asymmetrical Triangle (ISO)
(Fixed Width..... 2 mS rise time / 13 mS fall time)
Default Setting ..... Sine Square (SSQ)
Test Load(s)

Available Selection(s).....(3) 200, 500 and 1000 Ω ±1 %

Default Setting.....500 Ω

Amplitude

Pacer Load Selection .....500 Ω

Range.....0.05 mV_{peak} (50 V_{peak}) to 50.0 mV_{peak}

Accuracy.....±5 % of setting

Resolution .....0.05 mV_{peak} steps from 0.05 mV_{peak} to 0.95 mV_{peak}
0.50 mV_{peak} steps from 1.0 mV_{peak} to 50.0 mV_{peak}

Pacer Load Selection .....200 Ω

Range.....0.05 mV_{peak} (50 V_{peak}) to 20.0 mV_{peak}

Accuracy.....±5 % of setting

Resolution .....0.05 mV_{peak} steps from 0.05 mV_{peak} to 0.95 mV_{peak}
0.50 mV_{peak} steps from 1.0 mV_{peak} to 20.0 mV_{peak}

Pacer Load Selection .....1000 Ω

Range.....0.05 mV_{peak} (50 V_{peak}) to 100 $mV_{peak\text{-}to\text{-}peak}$

Accuracy.....±5 % of setting

Resolution .....0.05 mV_{peak} steps from 0.05 mV_{peak} to 0. 95 mV_{peak}
0.50 mV_{peak} steps from 1.0 mV_{peak} to 49.5 mV_{peak}
05.0 mV_{peak} steps from 50 mV_{peak} to 100 mV_{peak}

Default Setting .....2.5 mV_{peak}

Width

Range.....0.15 mS to 300 mS

Accuracy.....±5 % of setting

Selection Count 58

Resolution (Step Size).....0.05 mS steps from 0.15 mS to 0.95 mS
1.0 mS steps from 1.0 mS to 19.0 mS
5.0 mS steps from 20 mS to 95.0 mS
25 mS steps from 100 mS to 300 mS

Intended Pacemaker Type(s)

VVI (Atrial Pace and Sense Only)

Compatible Pulse Rates.....30 to 200 PPM

Noise Immunity Test

Test Type ..... Qualitative

Channels

Single ..... Atrial or Ventricular Only

Waveform ..... Sine Wave

Frequency ..... 50 and 60 Hz

Accuracy ..... 0.5 Hz

Active Output(s) ..... Selected atrial and / or ventricular channel test load

Output Selections

Atrial Channel Only

Ventricular Channel Only

ECG Signal ..... ECG Signal can be added to the selected Channel

Amplitude

Pacer Load Selection ..... 500 Ω

Range ..... 0.00 (OFF) to 100 $mV_{peak\text{-}to\text{-}peak}$

Accuracy ..... ±5 % of setting

Resolution ..... 5 $mV_{peak\text{-}to\text{-}peak}$ steps

Pacer Load Selection ..... 200 Ω

Range ..... 0.00 (OFF) to 40 $mV_{peak\text{-}to\text{-}peak}$

Accuracy ..... ±5 % of setting

Resolution ..... 5 $mV_{peak\text{-}to\text{-}peak}$ steps

Pacer Load Selection ..... 1000 Ω

Range ..... 0.00 (OFF) to 200 $mV_{peak\text{-}to\text{-}peak}$

Accuracy ..... ±5 % of setting

Resolution ..... 5 $mV_{peak\text{-}to\text{-}peak}$ steps

Refractory Period Test (Atrial Channel)

Test Selections

Paced Refractory Period (PRP)

Sensed Refractory Period (SRP)

Period ..... 20 to 500 mS

Accuracy ..... ±5 % of reading or ±1 mS whichever is greater

Resolution ..... ±1 LSD

Display Format ..... 3 digits

Physiological Simulation

Selection (Default)	Single Channel Simulation (A) Square Wave
Atrial Channel	Simulated P-wave
Width	1.0 mS
Amplitude	20.0 mV_{peak}
Active Outputs	Atrial Channel (4 mm Banana Jacks) Only

Additional Waveform Selections

Square (SQU)
Triangle (TRI)
Haversine (HSN)
Sine Square (SSQ)
Asymmetrical Triangle (ISO) (Fixed Width 2 mS rise time / 13 mS fall time)

Amplitude

Range	05 mV_{peak} (50 V_{peak}) to 50.0 mV_{peak}
Accuracy	±5 % of setting
Resolution (Step Size)	0.05 mV_{peak} steps: 0.05 mV_{peak} to 0.95 mV_{peak} 0.50 mV_{peak} steps: 1.0 mV_{peak} to 49.5 mV_{peak}

Width

Range	0.15 mS to 95.0 mS
Accuracy	±5 % of setting
Selection Count	50
Resolution (Step Size)	0.05 mS steps: 0.15 mS to 0.95 mS 1.0 mS steps: 1.0 mS to 19.0 mS 5.0 mS steps: 20 mS to 95.0 mS
Active Output	Atrial Channel (4 mm Banana Jacks) Only
Intended Pacemaker Types	AAI (Atrial Pace and Sense Only)
Compatible Pacemaker Rates	30 to 200 PPM
Available Test Load	500 Ω ±1 %

Refractory Period Test (Ventricular Channel)

Test Selections

Paced Refractory Period (PRP)
Sensed Refractory Period (SRP)

Period	20 to 500 mS
Accuracy	±5 % of reading or 1 mS whichever is greater

Resolution ..... ±1 LSD
Display Format ..... 3 digits

Physiological Simulation

Selection (Default) ..... Single Channel Simulation (V)
Square Wave
Ventricular Channel ..... Simulated R-wave
Width ..... 1.0 mS
Amplitude ..... 20 mV_{peak}
Active Outputs ..... Ventricular Channel
(4 mm Banana Jacks) Only
Available Test Load(s) ..... 500 Ω Only

Additional Waveform Selections

Square (SQU)
Triangle (TRI)
Haversine (HSN)
Sine Square (SSQ)
Asymmetrical Triangle (ISO) (Fixed Width2 mS rise time / 13 mS fall time)

Amplitude

Pacer Load Selection ..... 500 Ω
Range ..... 0.05 mV_{peak} (50 V_{peak}) to
50.0 mV_{peak}
Accuracy ..... ±5 % of setting
Resolution (Step Size) ..... 0.05 mV_{peak} steps from 0.05 mV_{peak} to
0.95 mV_{peak}
0.50 mV_{peak} steps from 1.0 mV_{peak} to
50.0 mV_{peak}
Default Setting ..... 20.0 mV_{peak}

Width

Range ..... 0.15 mS to 300 mS
Accuracy ..... 5 % of setting
Selection Count 58
Resolution (Step Size) ..... 0.05 mS steps from 0.15 mS to
0.95 mS
1.0 mS steps from 1.0 mS to 19.0 mS
5.0 mS steps from 20 mS to 95.0 mS
25 mS steps from 100 mS to 300 mS
Default Setting (mS) ..... 30 mS
Intended Pacemaker Types ..... VVI (Ventricular Pace and Sense
Only)
Compatible Pacemaker Rates ..... 20 to 200 PPM

DC Leakage Current

Test Type.....Quantitative
Measurement Range.....00.1 µA to 99.9 µA
Input Polarity.....Positive and Negative
Resolution.....1 LSD
Display Format.....3 digits plus decimal point
Test Selections
- Static.....Continuous measurement
- Pacemaker Power.....OFF
- Input Configurations.....Atrial+ and Atrial-
Ventricular+ and Ventricular-
Atrial+ and Ventricular- (third internal 500 Ω test load)
- Dynamic.....Gated measurement preceding the delivered pacemaker pulse.
- Pacemaker Power.....ON
- Input Configurations.....Atrial+ and Atrial-
Ventricular+ and Ventricular-
Atrial+ and Ventricular+ (third internal 500 Ω test load)

Current Drain Test

Test Type.....Quantitative
Measurement Ranges
- DC Current.....0.100 mA to .999 mA
1.00 mA to 9.99 mA
10.0 mA to 99.9 mA
- Polarity.....Positive or Negative
- Polarity Indicator.....+ or - symbol preceding the numeric value
- Resolution.....±1 LSD
- Display Format.....3 digits plus decimal point
- Accuracy.....±5 % of Reading 10 µA

Input DC Voltage
- Nominal.....±9 Volts
- Range.....5.0 Volts to 10.5 Volts
- Input Protection.....Short-circuit protection
- Protection Type.....Internal in-line fast-acting fuse rated at ½ Ampere.
- Selectable Testloads.....200 Ω, 500 Ω, and 1000 Ω

Battery Test Fixture ..... Includes the 9 volt battery supply and facilitates connection of Analyzer to the recessed battery terminals within the Medtronic 5388 and 5348 Temporary Pacemakers.

Long Term Test

Test Configuration ..... Atrial Channel or Ventricular Channel

Pulse Count Range ..... 999,999 (maximum)

Rate ..... 2 % to 20 % (10 % default)

Amplitude ..... 2 % to 20 % (10 % default)

Test Time (max) ..... 999:59:59 (hhh:mm:ss)

Maximum error Count 200

Test Termination ..... Manual or when maximum error count is sensed.

Testloads Selectable ..... 200 □, 500 □, or 1000 □

Interactive Pacer ECG Simulation

Simulates demand, continuous, non-capture, and non-function patient ECG activity.

Additional user-selectable parameters

PR Interval ..... 0.05 to 0.300 Seconds

Independent Capture / threshold ..... 1 mA to 25 mA (1 mA steps) for each pacemaker channel.

Available Testloads (500 Ω Default)

Atrial Channel

Selections ..... 200 Ω, 500 Ω, or 1000 Ω

Accuracy ..... ±1.0 % of selection

Power Rating ..... 2 Watts

Ventricular Channel

Selections ..... 200 Ω, 500 Ω, or 1000 Ω

Accuracy ..... ±1.0 % of selection

Power Rating ..... 2 Watts

Tracking ..... Atrial and ventricular channel settings are identical.

Accessories

Standard accessories and associated part numbers are listed in Table 1-3; optional accessories and associated part numbers are listed in Tables 1-4 through 1-8.

Table 1-3. Standard Accessories

Description	Part Number
Transvenous Test Lead Red (2 each)	2201166
Transvenous Test Lead Black (2 each)	2201153
9 V dc Load Test Cable	2392272
Operators Manual	2243306
PC Interface Cable Female DB-9 to Female DB-9	2392260
Nylon Carry Case	2392906
Universal-Input Battery Eliminator	2184298

Table 1-4. Pacemaker Disposable Electrode Adapters

Description All Pacemaker Disposable Electrode Adapters	Part Number
Physio-Control QUIK COMBO	2201095
Physio-Control QUIK PACE	2201088
Hewlett Packard CodeMaster	2201109
Marquette Medical Responder	2201111
MDE / MRL R2 / DAROX	2201127
Zoll NTP Series	2201130
Zoll PD and M-Series	2201148

Table 1-5. Serial Cables

Description	Part Number
PC Interface Cable Female DB-9 to Female DB-9	2200962
medTester Serial Interface Female DB-9 to Female DB-25	2200102

Table 1-6. Compatible Power Supply

Region of Operation	Part Number
Universal Power Supply 15V (90 to 264 VAC) IEC320 C6 3-wire	2184298
USA / CAN Power Cord IEC320 C5 3-wire	2198724
United Kingdom (UK) Power Cord IEC320 C5 3-wire	2201428
European Power Cord IEC320 C5 3-wire (SCHUKO)	2201437
Australia Power Cord IEC320 C5 3-wire	2201443

Table 1-7. Disposable Transcutaneous Pacemaker Adapters

Device Manufacturer Model/Designation	Part Number
Medtronic/Physio Control QUIK COMBO	2201095
Medtronic/Physio Control QUIK PACE	2201088
HP/Agilent Technologies Codemaster/HeartStream XL Series	2201109
GE Medical/Marquette Responder Series	2201111
MDE Medical Data Electronics MRL Medical Research Laboratories R2/DAROX	2201127
Zoll Medical NTP Series•	2201130
Zoll Medical PD and M Series (Multi- Function)	2201148

Table 1-8. High-Level Output Cables

Description	Part Number
Subminiature Phone Plug to BNC Cable (Oscilloscope Application)	2199932
Subminiature Phone Plug to 3-Conductor ¼" Phone Plug Cable (AA-900)	2200116

Chapter 2
Setup, Operation, and Maintenance

Contents **Page**

Setting Up the Analyzer 2-3
Connecting External Transcutaneous Pacemakers 2-3
Connecting External Transvenous Pacemakers 2-4
Load Test Cable Connector 2-4
RS-232 Serial Port Connector 2-5
High Level ECG Output Jack 2-5
Ventilation 2-5
Power Up Sequence 2-5
Transcutaneous Pacemaker Testing 2-7
Transvenous Pacemaker Testing 2-7
Utility Functions 2-7
Maintenance 2-8
Avoiding Damage 2-8
Cleaning 2-9
Service and Calibration 2-9
Packing Instructions 2-10
Shipping 2-10

Setting Up the Analyzer

The Analyzer utilizes an external plug-in universal power supply. It automatically operates with applied main voltages rated from 83 to 264 V ac or from the internal battery. No transformer taps, jumpers, or programming tabs are required for Analyzer operation. The Analyzer is shipped from the factory with the power supply configured for the desired (or specified) country or region.

If your Analyzer is equipped with an incompatible power supply configuration, contact the Fluke Biomedical Service Center regarding replacement/order adjustment. Compatible power supplies and associated part numbers are listed in the chapter "Introduction and Specifications."

Set up the Analyzer for initial operation by plugging in the power supply plug into the **CHARGER INPUT** located on the right side panel of the Analyzer.

Connecting External Transcutaneous Pacemakers

To facilitate the safe and convenient connection of the transcutaneous pacemaker to the Analyzer, optional disposable electrode adapters are available from Fluke Biomedical and are compatible with most device manufacturers. These adapters connect the external pacemaker to the 4 mm safety banana receptacle/jacks located on the Analyzer top panel and are listed, with their Fluke part numbers, in the chapter "Introduction and Specifications."

⚠ ⚠ Warning

To avoid injury to a patient, do not connect the Analyzer to a patient or equipment connected to a patient. The Analyzer is intended for equipment evaluation only and should never be used in diagnostics, treatment or in any other capacity where the Analyzer would come in contact with a patient.

Refer to the latest Fluke Biomedical price list for availability of optional electrode adapters.

Note

If desired, you may fabricate your own adapter cables by using comparable general-purpose test leads with 4 mm safety (male) banana plugs terminated with the requisite brand/designated electrode connector.

Connecting External Transvenous Pacemakers

Two identical pairs of transvenous pacemaker test leads are supplied as standard accessories with the Analyzer. These test leads are color-coded RED (Part Number 2201166) and BLACK (Part Number 2201153) for connection to the 4 mm safety banana receptacle/jacks located on the Analyzer top panel. To securely connect the external transvenous pacemaker to the Analyzer, these test leads incorporate 0.08" diameter pin probes compatible with external transvenous pacemaker output jacks/terminals.

Use these test leads to connect the output of the transvenous single-channel (atrial or ventricular) or dual-channel (atrial and ventricular) external pacemaker to the SigmaPace 1000.

⚠ ⚠ Warning

To avoid injury to a patient, do not connect the Analyzer to a patient or equipment connected to a patient. The Analyzer is intended for equipment evaluation only and should never be used in diagnostics, treatment or in any other capacity where the Analyzer would come in contact with a patient.

Load Test Cable Connector

The load test cable plugs directly into the Analyzer left side panel connector marked **CURRENT DRAIN TEST**. This standard accessory cable contains a nine-volt battery to power the external pacemaker.

Note

A 0.5 Amp (FAST-BLO) fuse protects the load test metering circuitry from an accidental short circuit or overload.

RS-232 Serial Port Connector

The RS-232 serial port is used to connect the Analyzer to a controller for remote operation. Refer to "Instrument Familiarity" for the location of this connector and to the "Remote Operation" chapter for instructions on how to operate the Analyzer remotely.

High Level ECG Output Jack

From the right-side panel, you can connect the high-level ECG output to a compatible oscilloscope, slave monitor, or to the Armstrong Medical Industries VIDEO ADAPTER RhythmSim™ 900 TV Interface Model AA-900. Use the high-level output cables listed in the chapter "Introduction and Specifications."

Ventilation

Heat generated during use is dissipated through ventilation slots on both the left and right side panels.

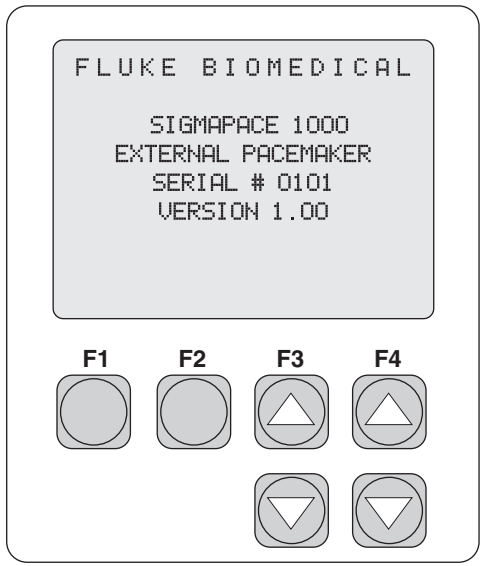
⚠ Caution

To avoid heat buildup damage to the Analyzer, do not block the ventilation slots during use or while the instrument is charging.

Power Up Sequence

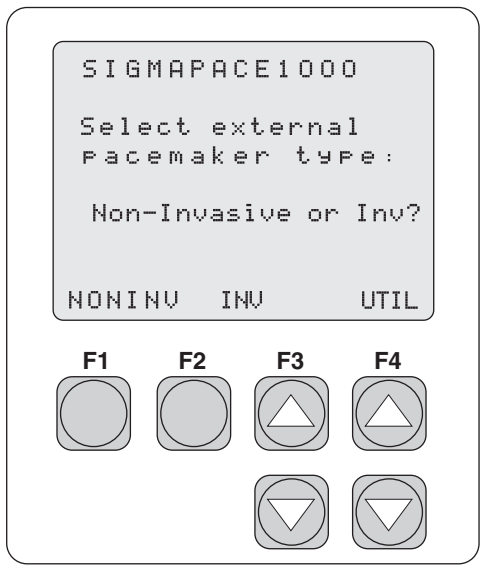
Take the following steps to power up the Analyzer.

1. Press and release the **ENT** / **POWER ON** key, located on the Analyzer top panel. The LCD momentarily displays the following screen.



eyr008.eps

The LCD then advances to the **Select external pacemaker type** screen:



eyr001.eps

2. From this screen, you can select one of the following options:
   - **F1 NONINV** to begin Non-Invasive (transcutaneous) external pacemaker testing.
   - **F2 INV** to begin Invasive (transvenous) external pacemaker testing.
   - **F4 UTIL** to access the Utility menu.

Note

*Use the **ESC** or **POWER OFF** key during operation to return to previous screens.*

Transcutaneous Pacemaker Testing

See the "Transcutaneous Pacemaker Testing" chapter for test options and specific directions.

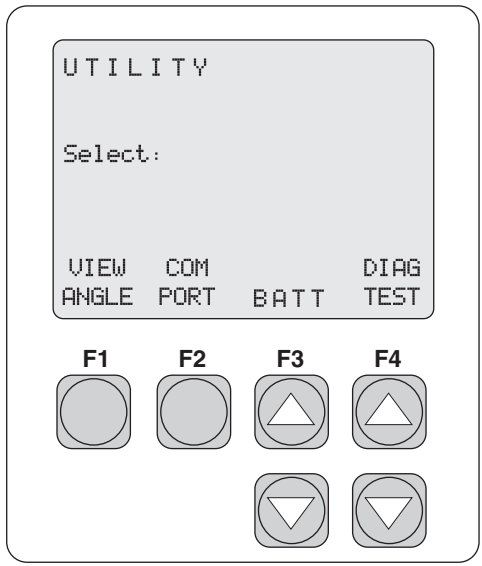
Transvenous Pacemaker Testing

See the "Transvenous Pacemaker Testing" chapter for test options and specific directions.

Utility Functions

To access the utility functions, do the following:

1. From the **Select external pacemaker type** screen, press **F4 UTIL**. The **UTILITY** screen displays:



eyr057.eps

1. Press **F1 VIEW ANGLE** to adjust the viewing angle.
2. Press **F2 COM PORT** to select baud rate.
3. Press **F3 BATT** to view battery voltage and charging status.
4. Press **F4 DIAG TEST** to select calibration and display test functions.

Maintenance

The Analyzer requires little maintenance or special care; however, it is a calibrated measuring instrument and should be treated as such. The following describes how to maintain the Analyzer and the method of company support.

Avoiding Damage

Do not drop the instrument or subject it to any mechanical abuse that could cause a shift in the calibrated settings.

⚠ Caution

To avoid damage to the Analyzer or adverse affects on its performance, do not expose the system to temperature extremes. Ambient temperatures should remain between 18 and 40 °C. System performance may be adversely affected if temperatures fluctuate above or below this range.

Cleaning

Clean the exterior of the Analyzer occasionally with a cloth dampened with a mild detergent solution. Take care to keep liquids out of the interior of the unit.

⚠ Caution

To avoid damage to the Analyzer or adverse affects on its performance, clean it only by gently wiping down with a clean, lint-free cloth dampened with a mild detergent solution. Do not immerse the unit.

Carefully wipe down the cables and inspect them for damage and deterioration of the insulation. Check the cable connections for integrity of the cable clamp and strain relief.

Service and Calibration

If your new Analyzer fails to operate successfully, please contact the Fluke Biomedical Service Center immediately, as indicated under "Warranty and Product Support."

⚠ Caution

To avoid damage to the Analyzer or adverse affects on its performance, allow only qualified technical personnel to service the Analyzer.

Calibration of the Analyzer by an authorized Fluke Biomedical Service Center is recommended. Fluke Biomedical Service Centers have the appropriate tools and procedures for performing calibrations as well as factory-authorized updates.

International customers should contact their Fluke Biomedical dealers for service/product support.

To obtain the name of your local dealer or service center, contact Fluke Biomedical as indicated under “Return Procedures, Repair and calibration.”

Packing Instructions

If calibration or repairs are required, return the Analyzer to the factory or the nearest service center.

1. Before returning the Analyzer for factory service, contact the Fluke Biomedical Service Center for a required Return Authorization Number.
2. Provide the following information:
    - The Analyzer serial number
    - The specific steps that reproduce your problem
    - A daytime phone number
    - Your name/company
    - A fax number (if available)
3. Pack the instrument carefully, using the original packing materials. If the original packing materials are not available, refer to “Return Procedures” for a list of preferred materials or contact Fluke Biomedical for replacement packing. Failure to pack the instrument properly could void your warranty.

Shipping

4. Place the Return Authorization Number in a prominent place on the outside of the packing box, and refer to the number in any correspondence with Fluke Biomedical Service.
5. Enclose your return address and Return Authorization Number.
6. Insure the unit for full retail value and ship to the nearest Fluke Biomedical service center.

Chapter 3
Transcutaneous Pacemaker Testing

Contents **Page**

Test Options 3-3
Output 3-4
Demand Mode 3-5
Asynchronous Mode 3-5
Amplitude Sensitivity 3-5
Line Frequency / Noise Immunity 3-6
Refractory Period 3-6
Paced Refractory Period (PRP) 3-6
Sensed Refractory Period (SRP) 3-7
Long Term Test 3-8
Interactive Pacemaker / ECG Simulation 3-9
Simulated ECG Rate 3-9
Adjustable Threshold Level 3-9
Operational Modes 3-9
Continuous 3-9
Non-Capture 3-9
Non-Function 3-10
Setup and Testing 3-10
Output 3-12
Demand Mode Pacemaker's Interaction with ECG Signal 3-14
Continuous Mode Pacemaker's Interaction with ECG Signal 3-15
Demand Mode Pacemaker's Ability to Sense ECG Activity 3-17
Amplitude of ECG Signal for Demand Mode Pacemaker 3-20
Pacemaker's Ability to Filter Line Noise 3-23
Purpose of the ECG Simulation Test 3-26
Long Term Tests 3-27

Test Options

The scheme for transcutaneous pacemaker testing is shown in Figure 3-1. The specified (or default) test load is pre-selected with each algorithm. If desired, you can easily select any test load (50 Ω to 1550 Ω in 50 Ω steps) with each measurement algorithm.

Ensure that you select a test load within the device manufacturer's specified operational range. Device-specific measurement algorithms are selectable for the following list of manufacturers:

- Physio-Control Lifepak Series (50 Ω)
- HP / Agilent Codemaster (400 Ω)
- GE / Marquette Responder Series (300 Ω)
- Medical Data Electronics (600 Ω)
- Medical Research Laboratories (500 Ω)
- Zoll Medical PD-Series (1000 Ω)
- Zoll Medical M-Series (100 Ω)

Tests requiring ECG simulation have three available active outputs:

- Low Level (2): 5 Lead: RL / N, RA / R, LA / L, LL / F, and V1 / C1
  Transthoracic: Across the selected ventricular test load
- High Level (1): Output Amplitude tracks low level Lead I (1000:1)
  + / - 5.0V-peak maximum amplitude
  Connector Type: Subminiature Phone Jack

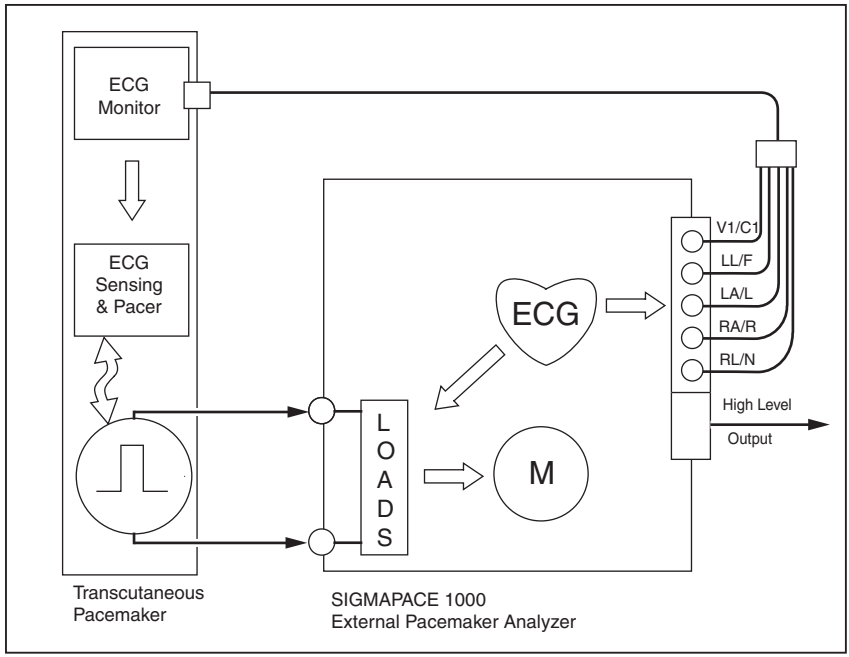


Figure 3-1. Scheme for Testing Transcutaneous Pacemakers

Output

The Analyzer measures the output of the transcutaneous pacemaker and displays the following parameters:

- Pulse Amplitude (milliamperes)
- Pulse Rate (pulses per minute
- Pulse Width (milliseconds)
- Pulse Energy (joules)

Demand Mode

This qualitative test verifies the demand mode pacemaker's ability to interact with a simulated ECG signal. The Analyzer first measures the pacemaker's applied pulse rate then computes "underdrive" and "overdrive" rates for the simulated ECG signal. Initially, the underdrive rate is 90 % of the applied pacemaker rate and the overdrive rate is 110 % of the applied pacemaker rate.

When testing the pacemaker, operating in the demand mode, output should be active (ON) with the underdrive ECG signal and then inhibited (OFF) when the overdrive ECG signal is selected. The rates of these underdrive and overdrive ECG signals can be adjusted across a wide physiological range using the Analyzer top panel controls.

Asynchronous Mode

This qualitative test verifies the continuous (or non-demand) mode pacemaker's ability to interact with a simulated ECG signal. The Analyzer first measures the pacemaker's applied pulse rate then computes underdrive and overdrive rates for the simulated ECG signal. Initially, the underdrive rate is 90 % of the applied pacemaker rate and the overdrive rate is 110 % of the applied pacemaker rate.

When testing the attached pacemaker, operating in the continuous (or non-demand) mode, output should be active (ON) when either the underdrive ECG signal or overdrive ECG signal is selected. The rates of these underdrive and overdrive ECG signals can be adjusted across a wide physiological range by the user.

Amplitude Sensitivity

This quantitative test determines the amplitude of the simulated ECG signal required by the demand mode pacemaker. The amplitude of the simulated ECG signal is increased in very small steps until the pacemaker senses it and inhibits the output pulse.

Line Frequency / Noise Immunity

This qualitative test verifies the pacemaker's ability to filter line frequency noise at either 50 or 60 Hz and sense a simultaneously applied simulated ECG signal. The user can change the amplitude of the line frequency noise, while the simulated ECG signal amplitude is fixed.

Refractory Period

These two related qualitative tests determine the demand mode pacemaker's ability to sense ECG activity immediately following either a paced event (PRP) or sensed ECG event (SRP).

Paced Refractory Period (PRP)

The Analyzer first measures the pacemaker's applied pulse rate, and then generates a simulated ECG signal within the expected PRP interval. See Figure 3-2. This coupling interval is slowly extended until the simulated ECG signal falls outside the PRP. The signal is then sensed by the pacemaker, causing the escape interval to reset. The result is a longer pacing pulse interval.

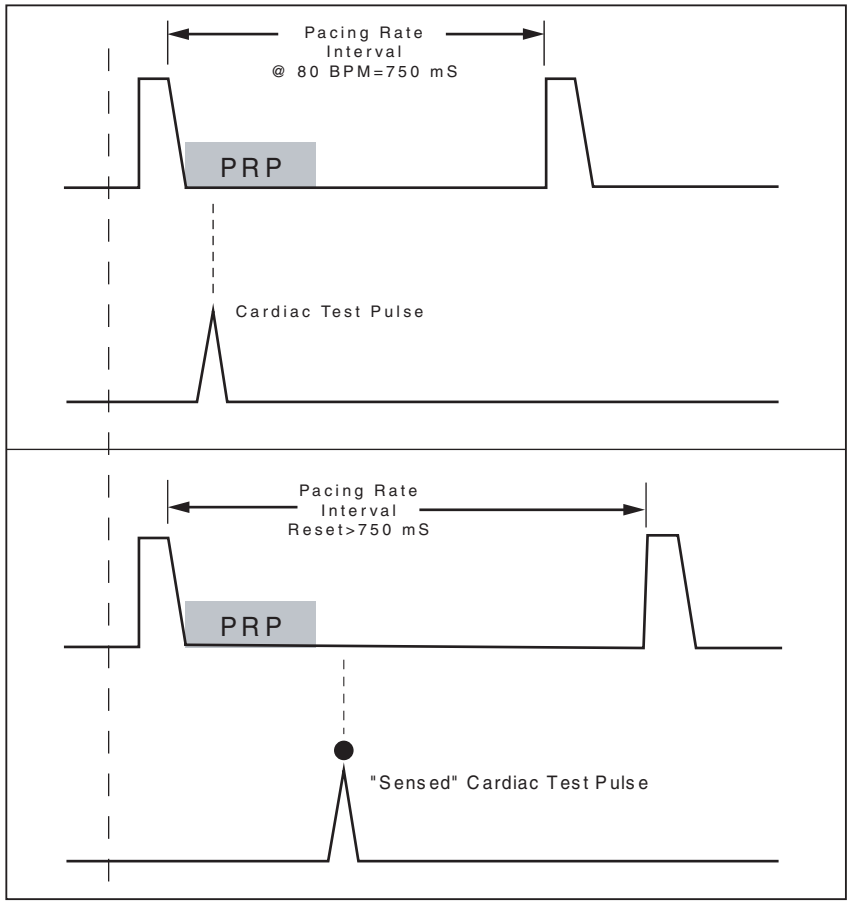


Figure 3-2. Paced Refractory Period

Sensed Refractory Period (SRP)

The Analyzer then generates a second simulated ECG signal immediately trailing the first simulated ECG signal used to determine the PRP. See Figure 3-3. This coupling interval is slowly extended until the simulated ECG signal falls outside the PRP. The signal is then sensed by the pacemaker, causing the escape interval to reset. The result is a longer pacing pulse interval.

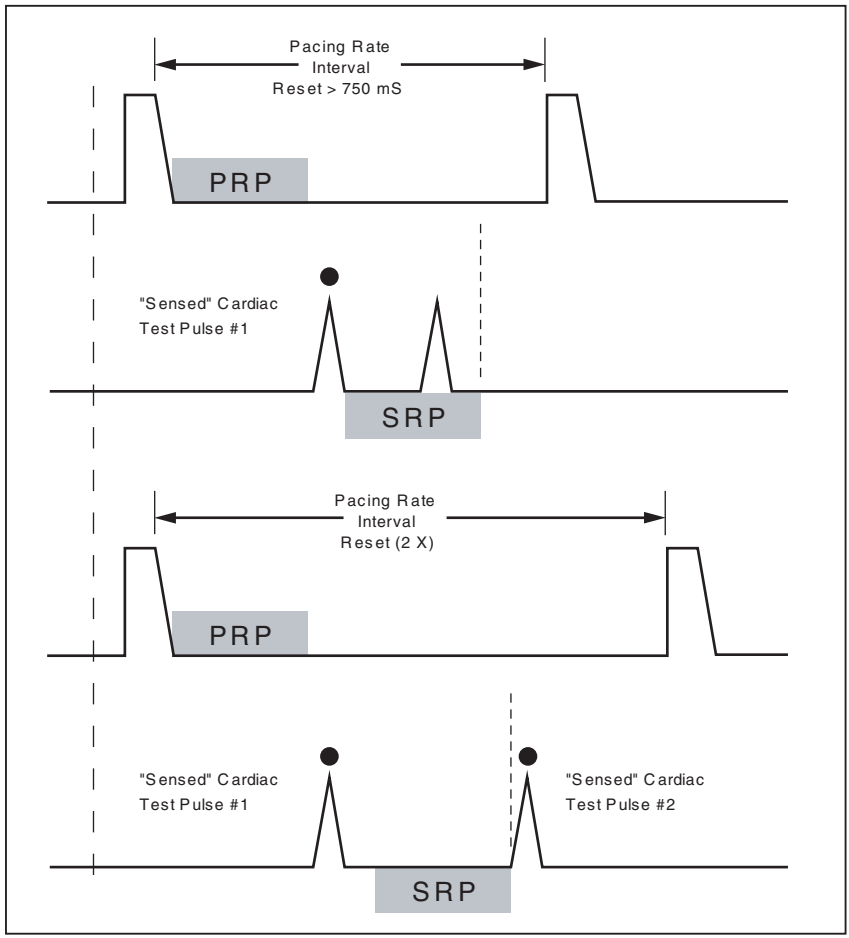


Figure 3-3. Sensed Refractory Period

Long Term Test

The overall stability of the pacemaker's pulse rate and amplitude are monitored continuously over an extended time period. Each measured pulse is compared to factory preset limits of 10 % for both monitored variables. Test limits are adjustable by the user.

Upon completion of the desired long-term test duration, the user can review pacemaker output pulses falling outside these test limits.

Interactive Pacemaker / ECG Simulation

The pacemaker responds to a wide range of simulated ECG signals using the Analyzer test feature. Several variables are user selectable to best simulate actual “real life” conditions.

Simulated ECG Rate

The Analyzer outputs either asystole or a normal sinus rhythm (NSR) at rates covering the bradycardia, normal, and tachycardia range.

Adjustable Threshold Level

When the pacemaker output current exceeds the threshold amplitude setting (in milliamperes), the Analyzer generates a simulated ventricular “paced” beat. The pacemaker output current level required to effect “ventricular capture” is selectable by the user.

Operational Modes

Three simulated operational modes are available in the Analyzer

Continuous

The user selects a rate, and the Analyzer generates a simulated ECG signal. The threshold interaction with the pacemaker is observed. No normal sinus rhythm (NSR) output is available in this operational mode.

Non-Capture

The Analyzer operates in “continuous mode”. However, every 8th expected “ventricular capture” event is skipped. No normal sinus rhythm (NSR) output is available in this operational mode.

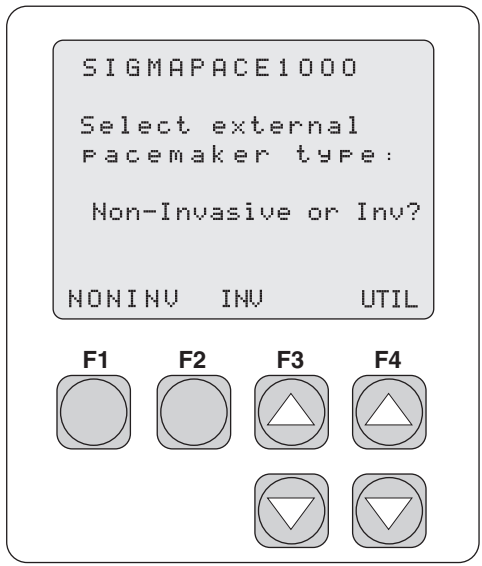
Non-Function

The Analyzer operates in “continuous mode” without “ventricular capture” events occurring. No normal sinus rhythm (NSR) output is available in this operational mode.

Setup and Testing

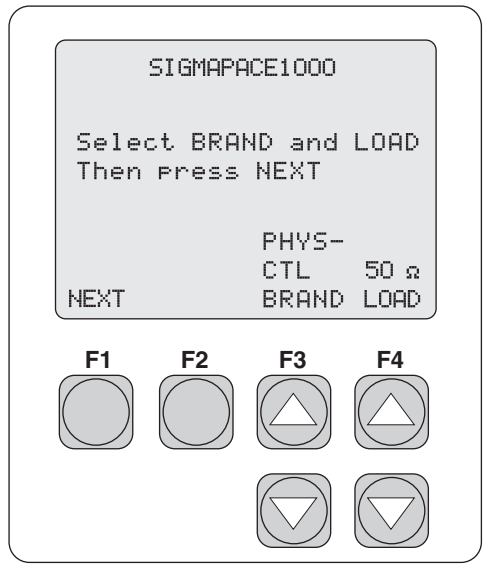
The following describes how to set up and test a transcutaneous pacemaker.

1. Start from the **Select external pacemaker type** screen.



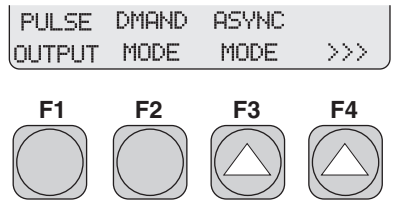
eyr009.eps

2. Press **F1 NONINV** to begin Non-Invasive (transcutaneous) pacemaker testing.



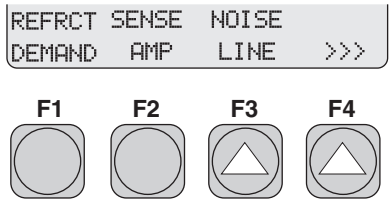
eyr010.eps

3. Press the **F3 PHYS-CTL BRAND UP** or **DOWN** arrow key to select instrument Brand / Model. The test load specified for each Brand / Model selection is automatically selected.
4. Press the **F4 UP** or **DOWN** arrow key to select the load. Test loads are available from 50 Ω to 1550 Ω in 50 Ω increments.
5. Press **F1 NEXT** to advance the display to the **SELECT TEST** menu. There are eight Non-Invasive tests.

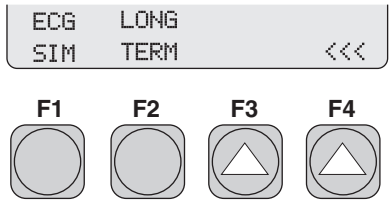


eyr011.eps

6. Press the **F4 >>> UP** arrow key to advance to the next screen and to see more available tests.



eyr012.eps

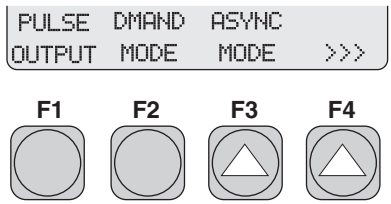


eyr013.eps

7. Press **ESC** to return to previous menu(s).

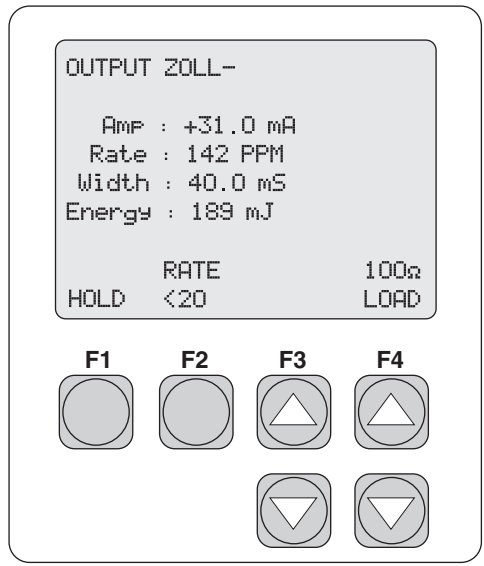
Output

The following test measures the output of the transcutaneous pacemaker.



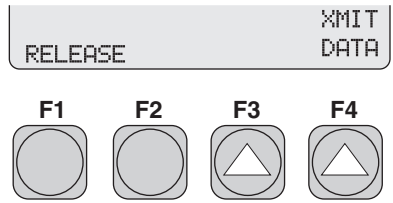
eyr014.eps

1. From the **SELECT TEST** menu, press **F1 PULSE OUTPUT**.



eyr015.eps

2. Press the **F4 LOAD UP** or **DOWN** arrow key to select the desired load.
3. Press **F1 HOLD** to advance the screen:

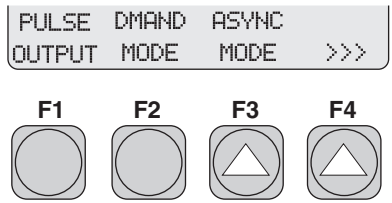


eyr016.eps

4. Press **F4 XMIT DATA** to transmit data through the serial port.
5. Press **F1 RELEASE** to release the hold and return to the **HOLD** screen.
6. Press **ESC** to return to previous menu(s).

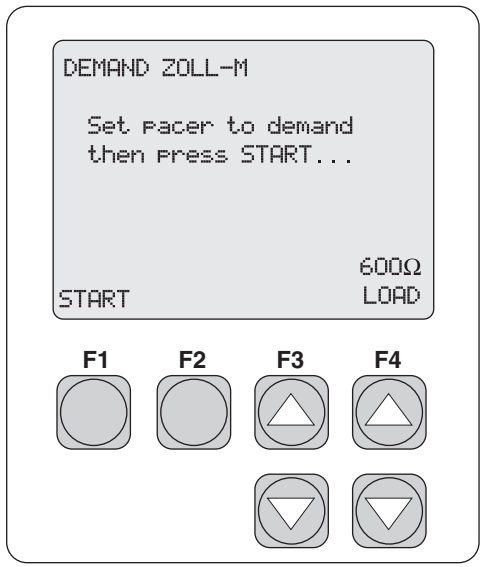
Demand Mode Pacemaker's Interaction with ECG Signal

The following test verifies the demand mode pacemaker's ability to interact with a simulated ECG signal.



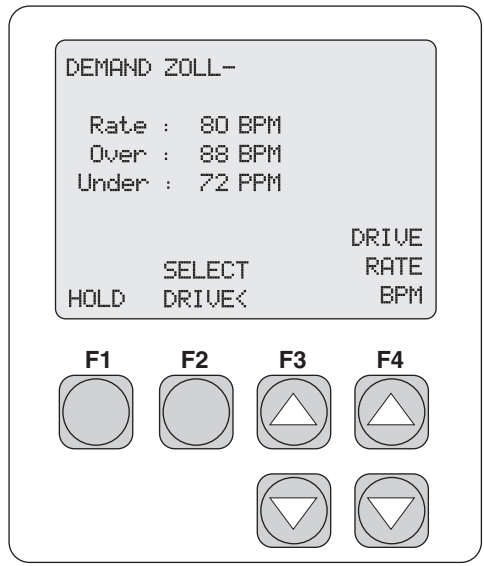
eyr014.eps

1. From the **SELECT TEST** menu, press **F2 DMAND MODE**.



eyr058.eps

2. Press the **F4 UP** or **DOWN** arrow key to select the desired load.
3. Press **F1 START** to advance the screen and start the test.

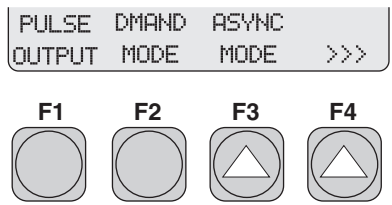


eyr017.eps

4. Press **F2 SELECT DRIVE<** to toggle between the Overdrive and Underdrive BPM rates.
5. Once a rate is selected, press **F4 DRIVE RATE BPM UP** or **DOWN** arrow key to adjust that rate.
6. Press **ESC** to return to previous menu(s).

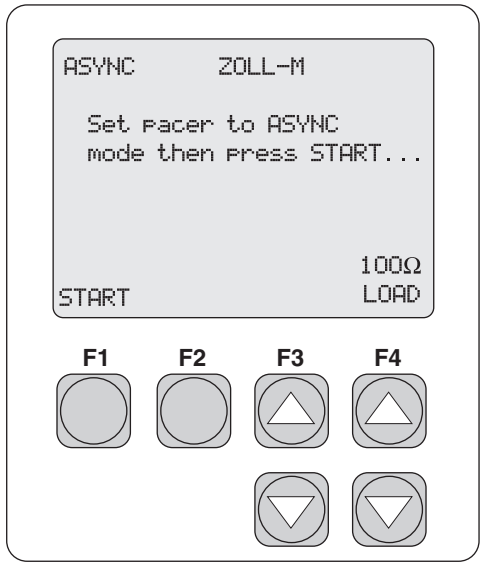
Continuous Mode Pacemaker's Interaction with ECG Signal

The following test verifies the continuous (or non-demand) pacemaker's ability to interact with a simulated ECG signal.



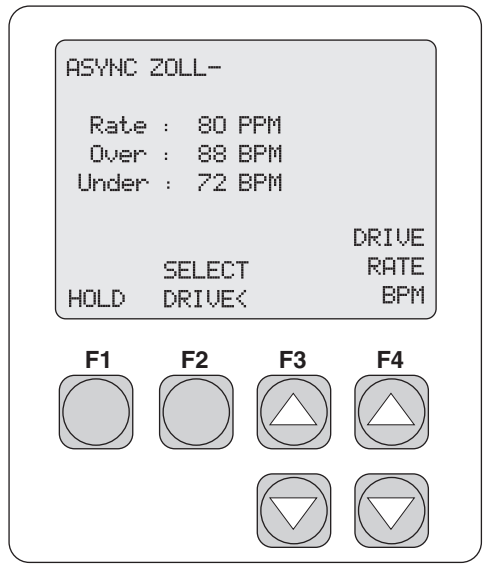
eyr014.eps

1. From the **SELECT TEST** menu, press **F3 ASYNC MODE**.



eyr059.eps

2. Press the **F4 LOAD UP** or **DOWN** arrow key to select the load.
3. Press **F1 START** to advance the screen and start the test.



eyr018.eps

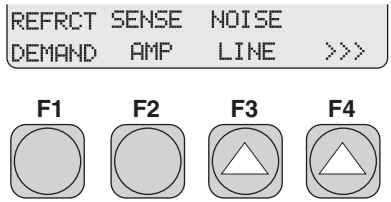
4. Press **F2 SELECT DRIVE<** to toggle between the Overdrive and Underdrive BPM rates.
5. Once a rate is selected, press **F4 DRIVE RATE BPM UP** or **DOWN** arrow key to adjust that rate.
6. Press **ESC** to return to previous menu(s).

Demand Mode Pacemaker's Ability to Sense ECG Activity

The two following, related tests, PRP and SRP, determine the demand mode pacemaker's ability to sense ECG activity immediately following either a paced event (PRP) or a sensed ECG event (SRP).

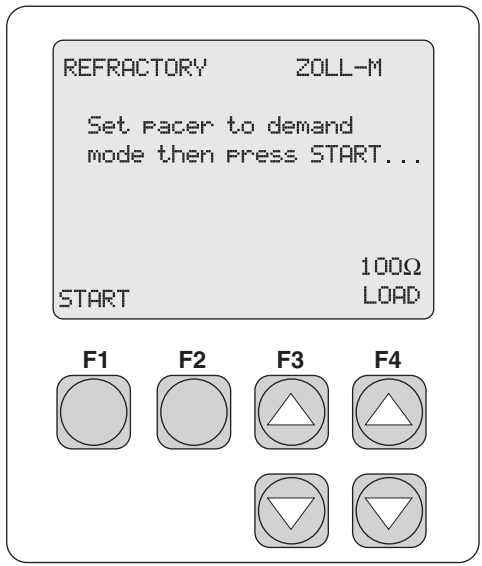
Note

A transcutaneous pacemaker must be set to Demand operation for these tests.



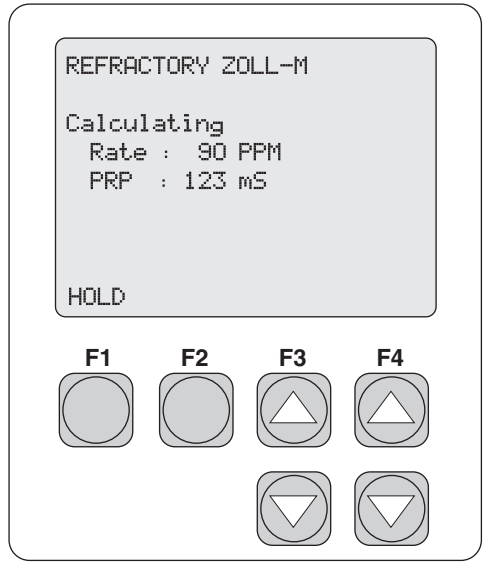
eyr012.eps

1. From the **SELECT TEST** menu, press **F1 REFRCT DEMAND**.



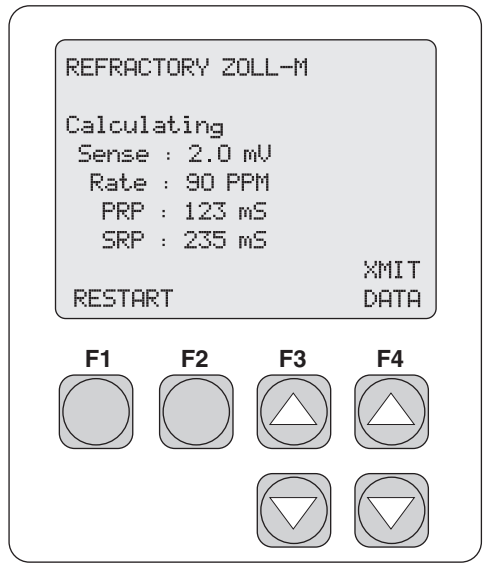
eyr060.eps

2. Press **F4 LOAD UP** or **DOWN** arrow key to select the load.
3. Press **F1 START** to advance screen and start the test.



eyr020.eps

After the calculations are complete, the following screen appears.

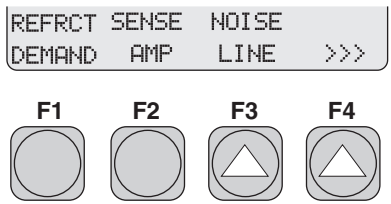


eyr021.eps

4. Press **F1 RESTART** to restart the test.
5. Press **F4 XMIT DATA** to transmit data.
6. Press **ESC** to return to previous menu(s).

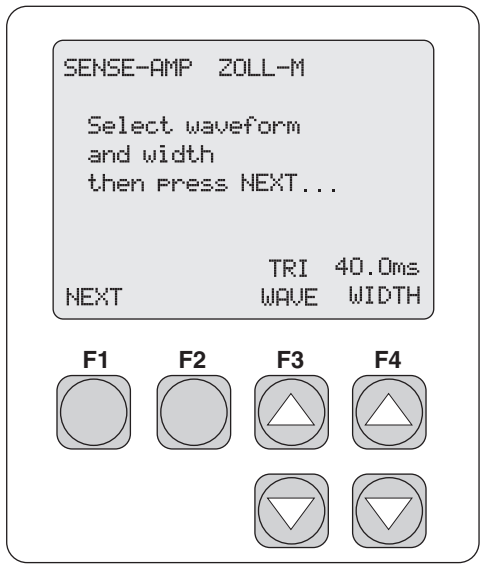
Amplitude of ECG Signal for Demand Mode Pacemaker

The following test determines the amplitude of the simulated ECG signal required by the demand mode pacemaker.



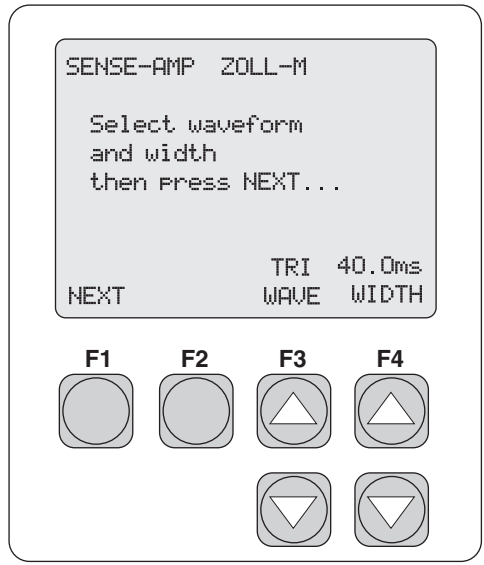
eyr012.eps

1. From the **SELECT TEST** menu, press **F2 SENSE AMP**.



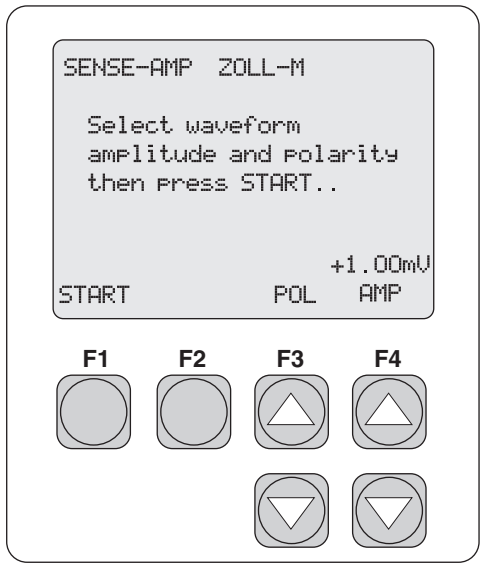
eyr062.eps

2. Press the **F4 LOAD UP** or **DOWN** arrow key to select the load.
3. Press **F1 NEXT** to advance the screen for waveform selection.



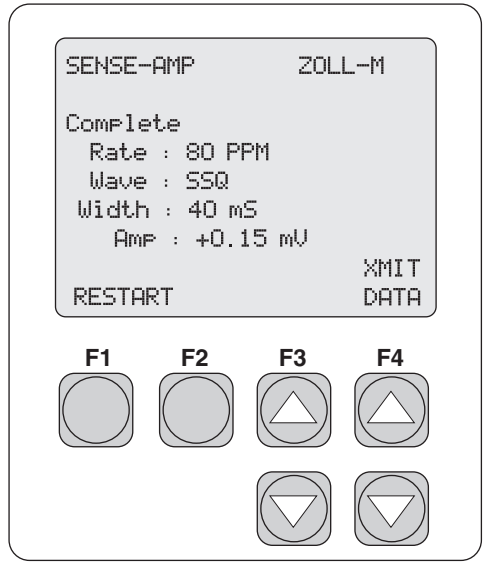
eyr062.eps

4. Press **F3 UP** or **DOWN** arrow key to select waveform type.
5. Press **F4 UP** or **DOWN** arrow key to select waveform width.
6. Press **F1 NEXT** for amplitude and polarity selection.



eyr063.eps

7. Press **F3 POLARITY UP** or **DOWN** arrow key to toggle the polarity.
8. Press **F4 AMPLITUDE** to adjust amplitude.
9. Press **F1 START** to initiate the test.

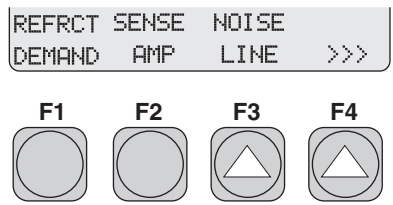


eyr022.eps

10. Press **F4 XMIT DATA** to transmit data.
11. Press **F1 RESTART** to begin the test again.
12. Press **ESC** to return to previous menu(s).

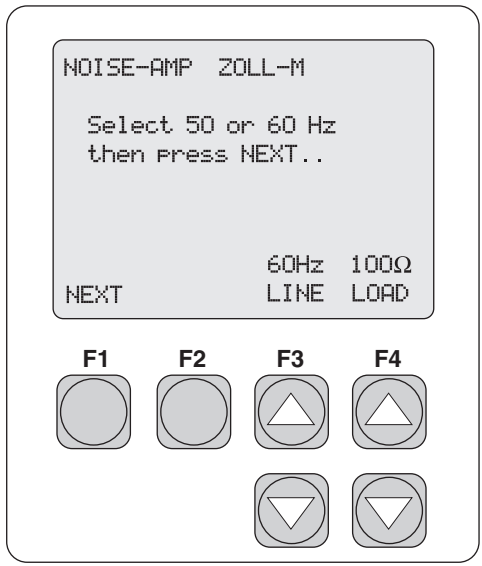
Pacemaker's Ability to Filter Line Noise

The following test measures a pacemaker's ability to filter line noise at either 50 or 60 Hz.



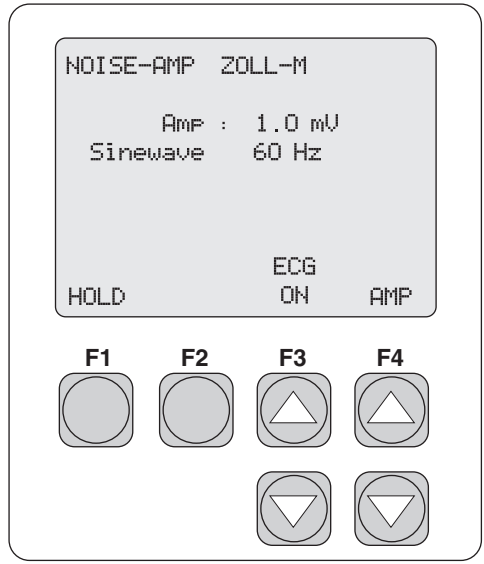
eyr012.eps

1. From the **SELECT TEST** menu, press **F3 NOISE LINE**.



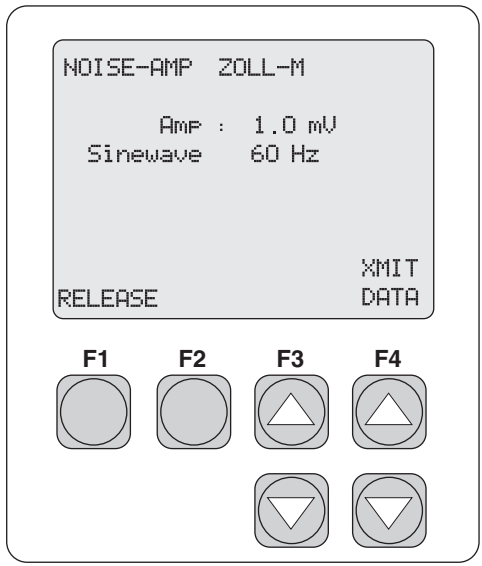
eyr064.eps

2. Press **F3 UP** or **DOWN** arrow key select the line frequency.
3. Press **F4 LOAD UP** or **DOWN** arrow key to select the load.
4. Press **F1 NEXT** to advance the screen.



eyr065.eps

5. Press **F3 ECG UP** or **DOWN** arrow key to toggle the **ECG** function **ON** or **OFF**.
6. Press **F4 AMP UP** or **DOWN** arrow key to adjust the amplitude of the line frequency.
7. Press **F1 HOLD** to advance the screen.

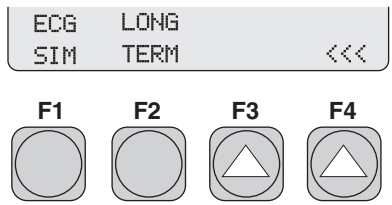


eyr066.eps

8. Press **F4 XMIT DATA** to transmit data.
9. Press **F1 RELEASE** to release the hold and return to the **HOLD** screen.
10. Press **ESC** to return to previous menu(s).

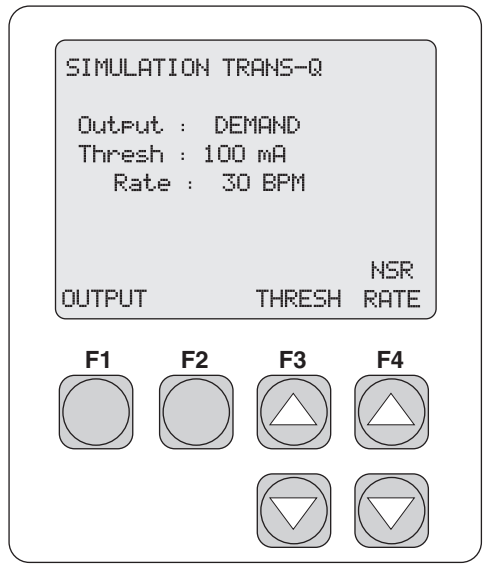
Purpose of the ECG Simulation Test

This test lets the technician check external pacemakers for basic operation, performance, and intermittent problems. Additionally, it is an excellent training tool for clinical staff in the setup and use of external pacemakers.



eyr013.eps

1. From the **SELECT TEST** menu, press **F1 ECG SIM**.



eyr025.eps

2. Press **F1 OUTPUT** to toggle among four simulated operational modes:
   - Demand
   - Continuous
   - Non-capture
   - Non-function.
3. Press **F3 THRESH UP** or **DOWN** arrow key to adjust the threshold amplitude.
4. Press **F4 NSR RATE UP** or **DOWN** arrow key to adjust the NSR rate.

Note

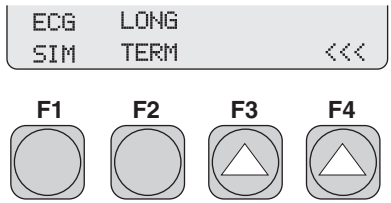
The NSR rate function is active only during the demand mode of operation.

Long Term Tests

The overall stability of the pacemaker's pulse rate and amplitude are monitored continuously over an extended period of time. The user enters the desired target values for these two parameters into the Analyzer. This program

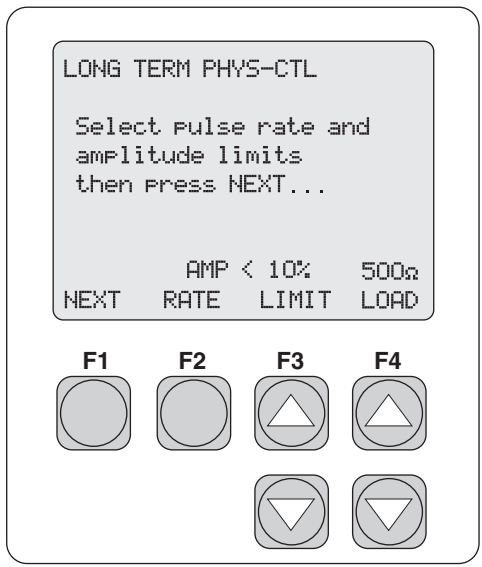
flexibility allows the user to enter either the actual test pacemaker values or the selected rate and amplitude settings.

Deviation values are independently selectable from 2 % to 20 % in 1 % increments. The Analyzer compares these incoming pacer pulses to the target values. When the long-term test is complete, output pulses from the pacemaker that were not within the selected limits may be reviewed.



eyr013.eps

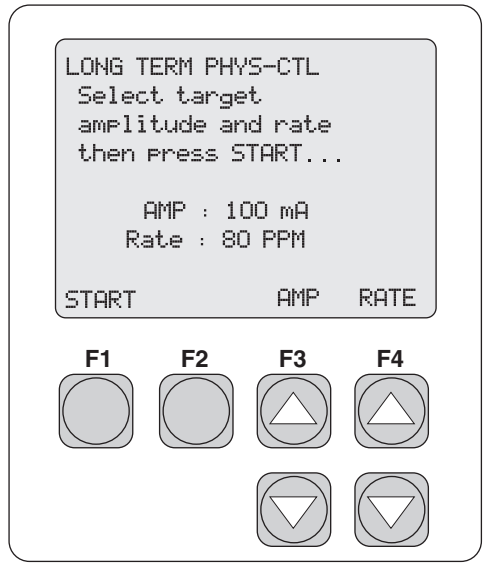
1. From the **SELECT TEST** menu, press **F2 LONG TERM**.



eyr026.eps

2. Press **F2 RATE** to toggle between pulse rate and amplitude. This parameter works with the **LIMIT** parameter to assign limits to both.

3. For each, pulse rate and amplitude, press **F3 LIMIT UP** or **DOWN** arrow key to select the limit value.
4. Press **F4 LOAD UP** or **DOWN** arrow key to select the load.
5. Press **F1 NEXT** to advance the screen.



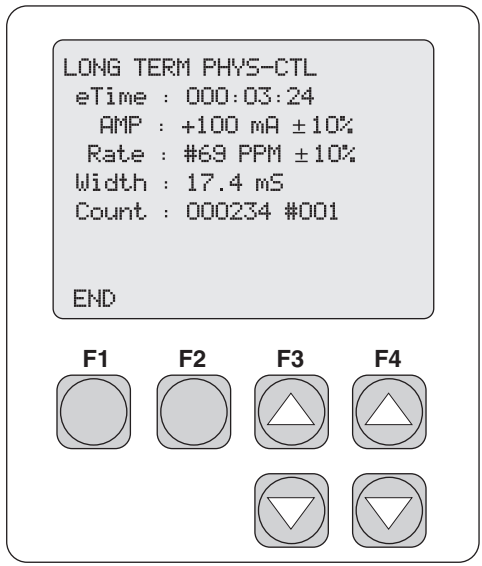
eyr027.eps

6. Press **F3 AMP UP** or **DOWN** arrow key to adjust the amplitude.
7. Press **F4 RATE UP** or **DOWN** arrow key to adjust the rate.

Note

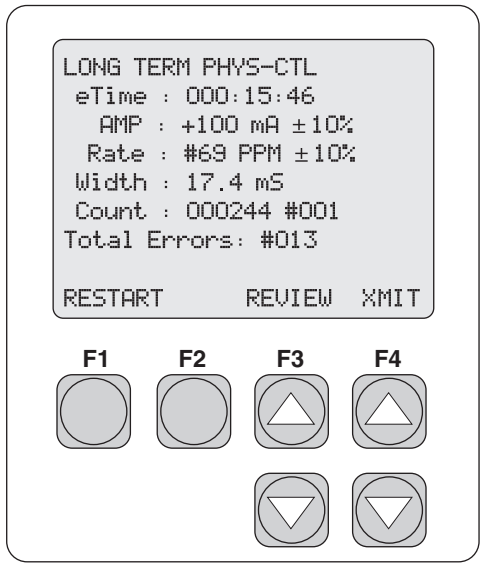
Target values for amplitude and rate must be entered for the test to perform correctly.

8. Press **F1 START** to advance the screen and start the test.



eyr028.eps

9. Press **F1 END** to end the test.



eyr029.eps

10. Press **F3 REVIEW UP** or **DOWN** arrow key to view deviations falling outside the selected deviation values for rate and amplitude.

    Up to 200 deviations will be stored in the Analyzer memory. Any long term test exceeding 200 deviations is automatically terminated. The pulse width at the "out of limit" pacemaker pulse is also reported.

11. Press **F4 XMIT** to transmit data.
12. Press **F1 RESTART** to restart the test.
13. Press **ESC** to return to previous menu(s).

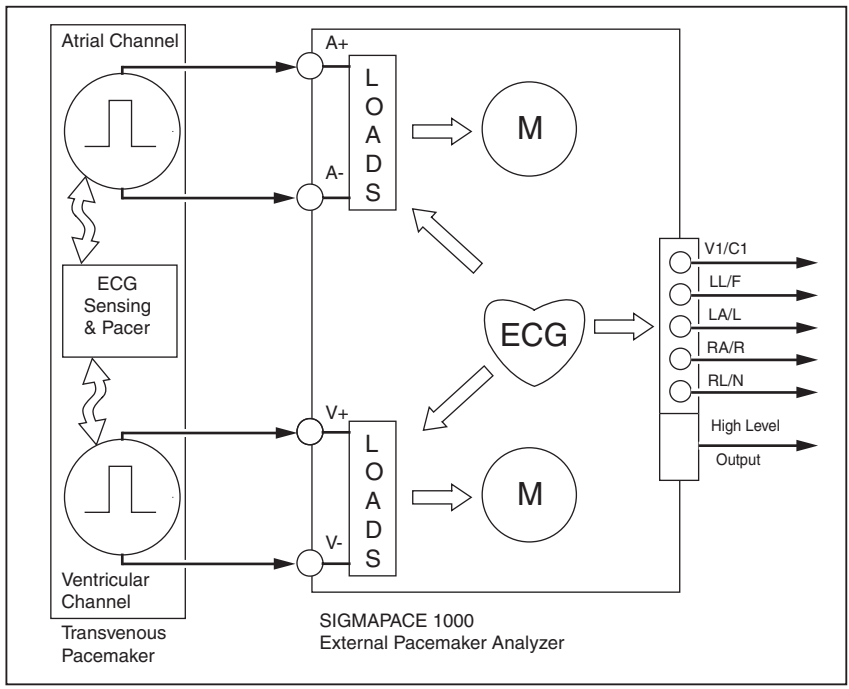
Chapter 4
Transvenous Pacemaker Testing

Contents **Page**

Test Options 4-3
Output 4-4
Demand Mode 4-4
Asynchronous Mode 4-4
Amplitude Sensitivity 4-5
Line Frequency / Noise Immunity 4-5
Refractory Period 4-5
Paced Refractory Period (PRP) 4-5
Sensed Refractory Period (SRP) 4-5
Interactive Pacemaker/ ECG Simulation 4-6
Simulated ECG Rate 4-6
PR Interval 4-6
Adjustable Threshold Level 4-6
Operational Modes 4-6
Continuous 4-6
Non-Capture 4-7
Non-Function 4-7
DC Leakage 4-7
Static Tests (Pacemaker Power OFF): 4-8
Dynamic Tests (Pacemaker Power ON): 4-9
Current Drain Test 4-9
Long Term Test 4-11
Setup and Testing 4-11
Output 4-13
Demand Mode and Dual-channel (AV) ECG Signal 4-16
Continuous Mode and Dual-channel (AV) ECG Signal 4-18
Demand Mode Pacemaker's Ability to Sense ECG Activity 4-20
Amplitude of ECG Signal for a Demand Mode Pacemaker 4-23
Pacemaker's Ability to Filter Line Noise 4-28
DC Leak Test 4-31
DC Load Test 4-34
ECG Simulation Test 4-36
Long Term Tests 4-38

Test Options

The scheme for transcutaneous pacemaker testing is shown in Figure 4-1.The measurement algorithms, protocols, and default waveform selections are based on the requirements published by Medtronic for their Model 5388 dual chamber temporary (external) pacemaker. Waveform selections for other brands and models of pacemakers are available in the Analyzer menus. Typically, transvenous pacemaker measurements are specified at a test load setting of 500 Ω, which is the Analyzer default setting. For most transvenous pacemaker tests, two additional loads of 200 Ω and 1000 Ω are also available. The test load resistance values track for both the atrial and ventricular channels.



eyr005.eps

Figure 4-1. Scheme for Testing Transvenous Pacemakers

Output

The Analyzer measures the output of the transvenous pacemaker, and displays the following parameters:

- Pulse Amplitude = milliamperes
- Pulse Rate = pulses per minute
- Pulse Width = milliseconds
- AV Delay = milliseconds
- Voltage = volts
- Energy = joules

To view these parameters, three choices are available from the menu: A+V Channels, A Channel Only, and V Channel Only.

Demand Mode

Tests are performed simultaneously for both atrial and ventricular channels. This qualitative test checks the demand mode pacemaker's ability to interact with a simulated dual-channel (AV) ECG signal. The Analyzer first measures the pacemaker's applied pulse rate, then computes "underdrive" and "overdrive" rates for the simulated dual-channel (AV) ECG signal. Initially, the underdrive rate is 90 % of the applied pacemaker rate, and the overdrive rate is 110 % of the applied pacemaker rate. When testing the attached pacemaker, operating in the demand mode, output should be active (ON) with the underdrive ECG signal, and then inhibited (OFF) when the overdrive ECG signal is selected. The rates of these underdrive and overdrive ECG signals can be adjusted across a wide physiological range.

Asynchronous Mode

Tests are performed simultaneously for both atrial and ventricular channels. This qualitative test checks the continuous (or non-demand) mode pacemaker's ability to interact with a simulated dual-channel (AV) ECG signal. The Analyzer first measures the pacemaker's applied pulse rate and then computes "underdrive" and "overdrive" rates for the simulated ECG signal. Initially, the underdrive rate is 90 % of the applied pacemaker rate and the overdrive rate is 110 % of the applied pacemaker rate. When testing the attached pacemaker, operating in the continuous (or non-demand) mode, output should be active

(ON) when either the underdrive ECG signal or overdrive ECG signal is selected. The rates of these underdrive and overdrive ECG signals can be adjusted across a wide physiological range by the user.

Amplitude Sensitivity

Tests are performed independently for the atrial and ventricular channels. This quantitative test determines the required amplitude of the simulated ECG signal to be detected by the demand-mode pacemaker. The amplitude of the simulated ECG signal is increased in very small steps until the pacemaker senses it and inhibits the output pulse.

Line Frequency / Noise Immunity

Tests are performed in two formats: atrial channel only and ventricular channel only. This qualitative test checks the pacemaker's ability to filter line frequency noise at either 50 or 60 Hz, and sense a simultaneously applied simulated ECG signal. The user can change the amplitude of both the line frequency noise. The simulated ECG signal amplitude is fixed.

Refractory Period

Tests are performed independently for the atrial and ventricular channels. These two related qualitative tests determine the demand mode pacemaker's ability to sense ECG activity immediately following either a paced event (PRP) or sensed ECG event (SRP).

Paced Refractory Period (PRP)

The Analyzer first measures the pacemaker's applied pulse rate, then generates a simulated ECG signal within the expected PRP interval. This coupling interval is slowly extended until the simulated ECG signal falls outside the PRP at which time it is sensed by the pacemaker, resetting the escape interval, resulting in a longer pacing pulse interval.

Sensed Refractory Period (SRP)

The Analyzer now generates a second simulated ECG signal immediately trailing the first simulated ECG signal used to determine the PRP. This

coupling interval is slowly extended until the simulated ECG signal falls just outside the SRP at which time it is sensed by the pacemaker, resetting the escape interval, resulting in a longer pacing pulse interval.

Interactive Pacemaker/ ECG Simulation

Tests are performed simultaneously for both atrial and ventricular channels. The response of the pacemaker to a wide range of simulated ECG signals is demonstrated using this Analyzer test feature. Several variables are user selectable to best simulate actual "real life" conditions.

Simulated ECG Rate

The Analyzer outputs either asystole or a normal sinus rhythm (NSR) at rates covering the bradycardia, normal, and tachycardia range.

PR Interval

The PR interval of the above ECG waveform complex is also user-selectable.

Adjustable Threshold Level

When the measured pacemaker output current exceeds the threshold amplitude setting (in milliamperes), the Analyzer outputs a simulated ventricular "paced" beat. The pacemaker output current level required to effect "ventricular capture" is selectable by the user.

Operational Modes

Three simulated operational modes are available in the Analyzer

Continuous

The user selects a rate, and the Analyzer generates a simulated ECG signal. The threshold interaction with the pacemaker is observed.

Non-Capture

The Analyzer operates in the above continuous mode. However, every 8th expected ventricular capture event is skipped.

Non-Function

The Analyzer operates in the above continuous mode. However no ventricular capture events occur.

DC Leakage

The integrity of the pacemaker's final output stage is evaluated during these leakage tests. See Figure 4-2. Over time, the pacemaker's active and passive electronic components can deteriorate and possibly couple dc voltage potentials to its final output stage.

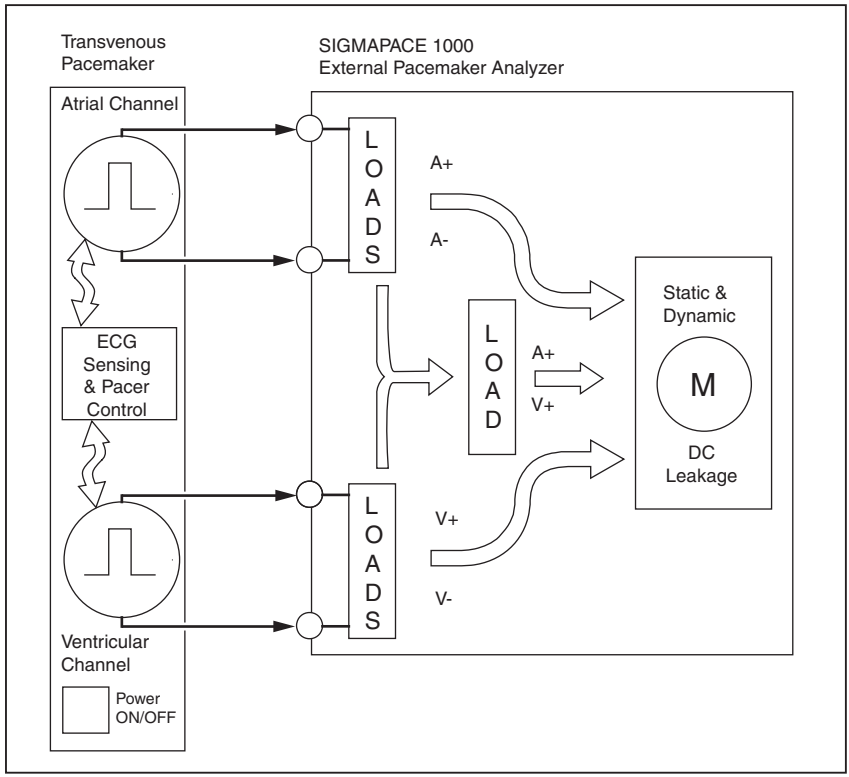


Figure 4-2. DC Leakage Testing

Potentially harmful dc levels can be detected using the various test configurations described below:

Static Tests (Pacemaker Power OFF):

These tests continuously measure dc leakage as follows:

- Atrial Channel: dc leakage across the atrial channel 500 Ω test load.
- Ventricular Channel: dc leakage across the ventricular channel 500 Ω test load.
- AV Channel: dc leakage across an auxiliary 500 Ω test load connected to the +atrial and +ventricular outputs.

Dynamic Tests (Pacemaker Power ON):

These tests are triggered measurements of dc leakage, measured prior to the specific output pulse as follows:

- Atrial Channel: dc leakage across the atrial channel 500 Ω test load.
- Ventricular Channel: dc leakage across the ventricular channel 500 Ω test load.
- AV Channel: dc leakage across an auxiliary 500 Ω test load connected to the +atrial and +ventricular outputs.

Note

Refer to the check out procedure for your specific pacemaker regarding testing protocols and limits for these dc leakage tests.

Current Drain Test

This test measures the load current drawn by the pacemaker from a 9 volt source. See Figure 4-3. A load test cable (Part # 2201074) is provided with the Analyzer as a standard accessory to facilitate connections to the recessed battery terminals of the Medtronic 5388 and 5348.

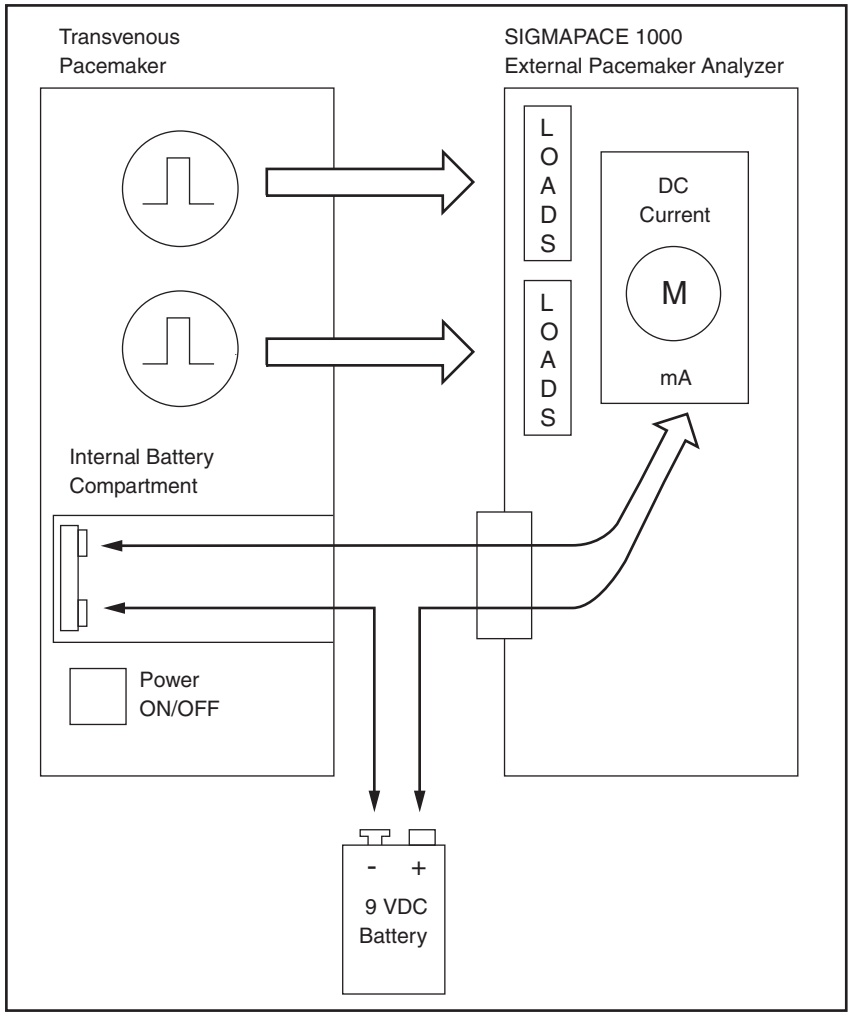


Figure 4-3. Current Drain Test

Readings are made in three pacemaker operating modes:

- Pacemaker Power OFF
- Pacemaker Power ON and Display Backlight OFF
- Pacemaker Power ON and Display Backlight ON

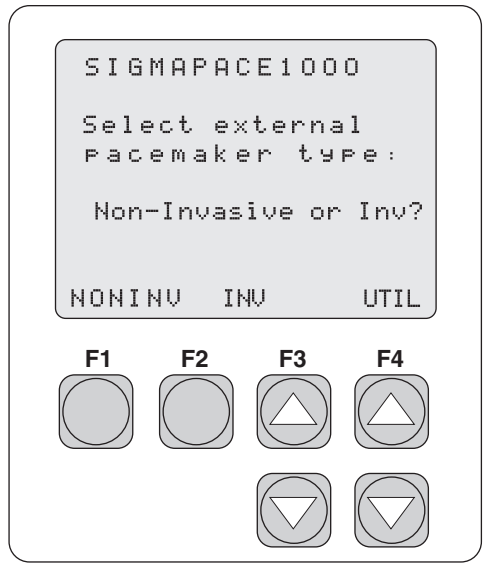
Standard test leads or short jumpers can be used to make connections on other brands and models of pacemakers.

Long Term Test

Tests are performed for only one channel at a time. The overall stability of the pacemaker's pulse rate and amplitude are monitored continuously over an extended time period. The user can independently input desired test limits for amplitude and rate (2-20) or use the factory default 10 % limits. Upon completion of the desired long-term test duration, the user can review pacemaker output pulses falling outside these test limits.

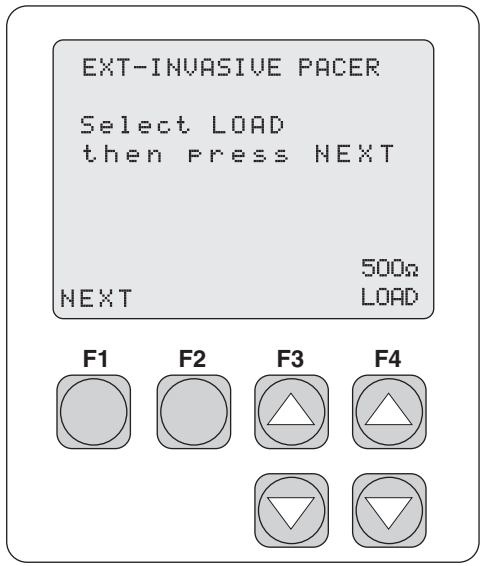
Setup and Testing

The following describes how to set up and test a transvenous pacemaker.



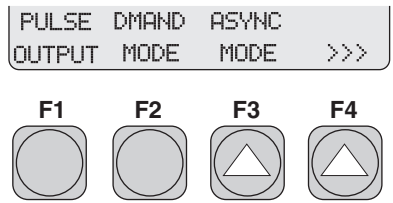
eyr001.eps

1. From the **Select external pacemaker type** screen, press **F2 INV** to begin Invasive (transvenous) pacemaker testing.



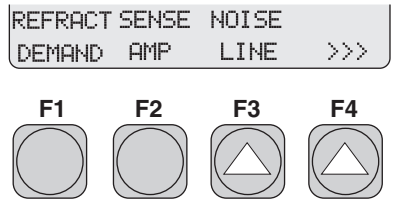
eyr031.eps

2. Press the **F4 LOAD UP** or **DOWN** arrow key to select the desired load. Test loads are available at 200, 500, and 1000 Ohms. Both atrial and ventricular test loads are set simultaneously to the selected value.
3. Press **F1 NEXT** to advance the display to the **SELECT TEST** menu. There are ten available Invasive tests.

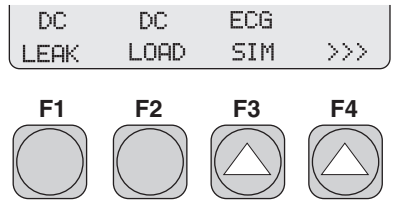


eyr032.eps

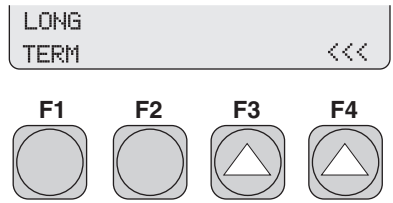
4. Use the **F4 >>> UP** arrow key to navigate through the available test selections.



eyr033.eps



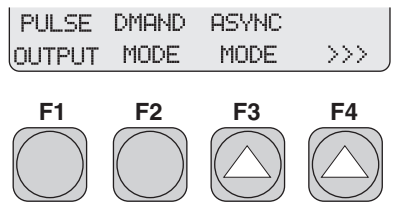
eyr034.eps



eyr035.eps

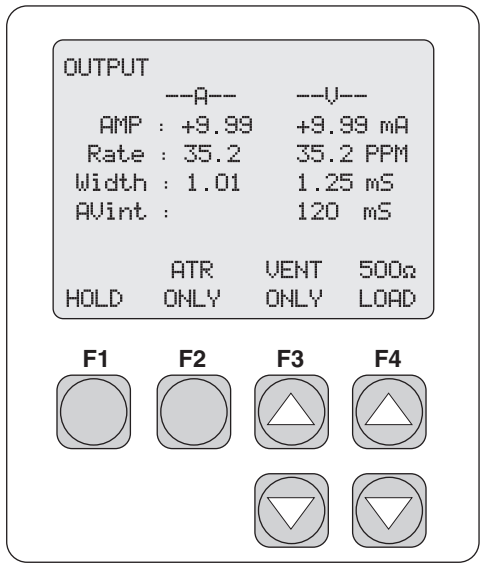
Output

The following test measures the output of the transvenous pacemaker.



eyr032.eps

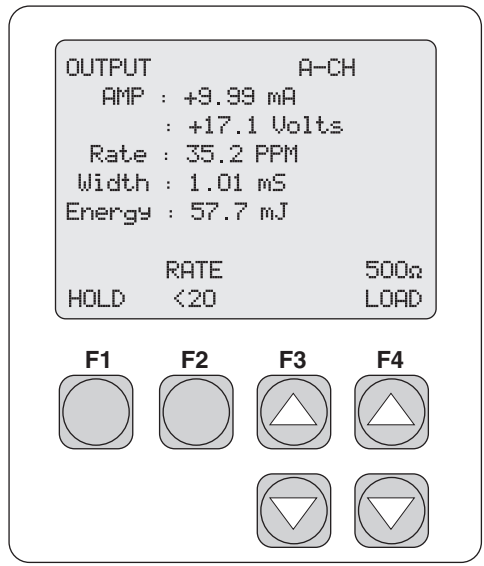
1. From the **SELECT TEST** menu, press **F1 PULSE OUTPUT**.



eyr037.eps

2. Select the desired configuration:
   - Press **F2 ATR ONLY** to display only atrial channel data.
   - Press **F3 VENT ONLY** to display only ventricular channel data.
3. Press **F4 LOAD UP** or **DOWN** arrow key to simultaneously select the desired test load for the atrial and ventricular channels.

   The atrial and ventricular channels independently autorange to best measure the incoming pacemaker activity. This **OUTPUT** display can be used to display single channel atrial, single channel ventricular, and dual channel atrial and ventricular pacemaker activity. The unused channel goes blank if no pacemaker activity is sensed.
4. Press **F2 ATR ONLY** or **F3 VENT ONLY** to display the following types of information (the example is atrial channel):



eyr038.eps

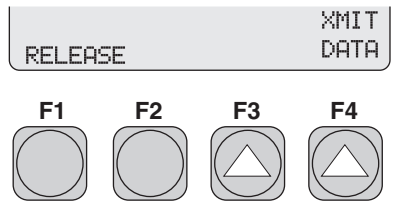
6. Press **F2 RATE** to toggle between **NORM** and **<20.**

Note

*The **RATE** <20 is used to measure pacer activity under the rate of 20 PPM. The sampling time is extended to accommodate this lower rate.*

7. Press **F4 LOAD UP** or **DOWN** arrow key to select the desired load for the selected channel.

8. Press **F1 HOLD** to advance the screen:



eyr016.eps

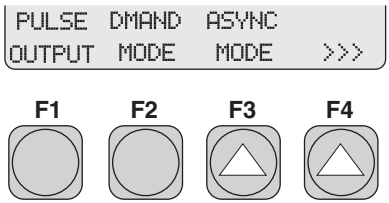
9. Press **F4 XMIT DATA** to transmit data through the serial port.

10. Press **F1 RELEASE** to release the hold and return to the **HOLD** screen.

11. Press **ESC** to return to previous menu(s).

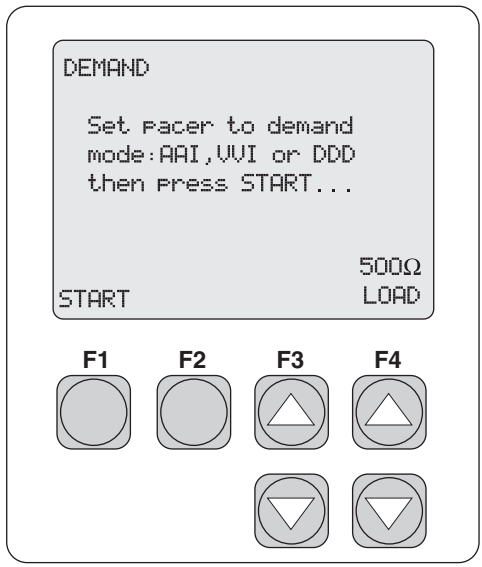
Demand Mode and Dual-channel (AV) ECG Signal

The following test measures the demand mode pacemaker's ability to interact with a simulated dual-channel (AV) ECG signal.



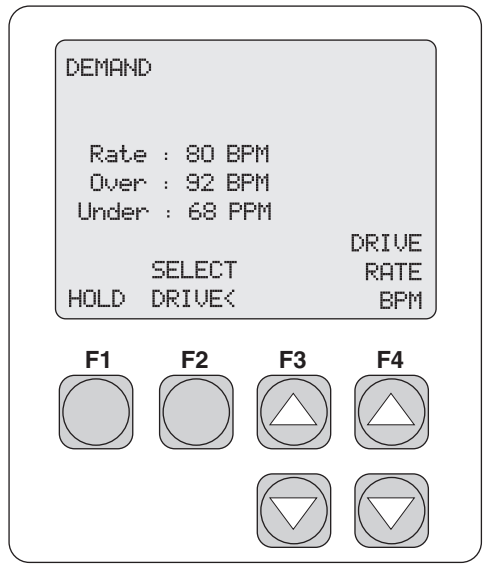
eyr032.eps

1. From the **SELECT TEST** menu, press **F2 DMAND MODE**.



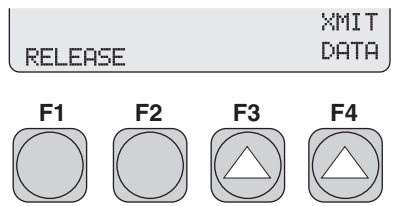
eyr067.eps

2. Press **F4 LOAD UP** or **DOWN** arrow key to select the load.
3. Press **F1 START** to advance the screen and start the test.



eyr039.eps

4. Press **F2 SELECT DRIVE<** to toggle between the **Over** and **Under** BPM rates.
5. Once a rate is selected, press **F4 DRIVE RATE BPM UP** or **DOWN** arrow key to adjust the rate.
6. Press **F1 HOLD** to advance the screen:

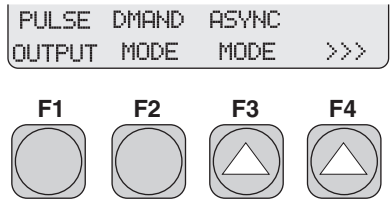


eyr016.eps

7. Press **F4 XMIT DATA** to transmit data through the serial port.
8. Press **F1 RELEASE** to release the hold and return to the **HOLD** screen.
9. Press **ESC** to return to previous menu(s).

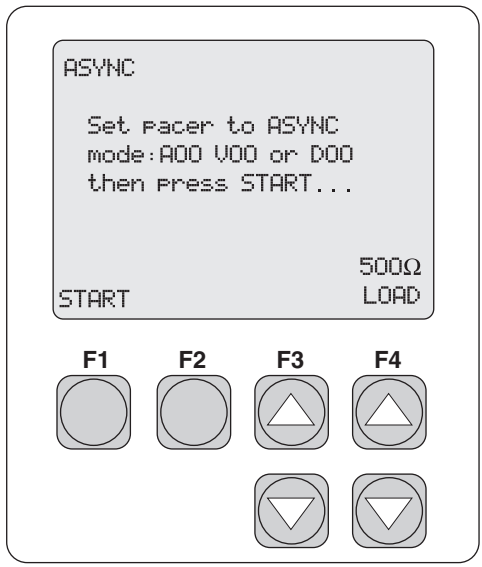
Continuous Mode and Dual-channel (AV) ECG Signal

The following test measures the continuous (or non-demand) pacemaker's ability to interact with a simulated dual-channel (AV) ECG signal.



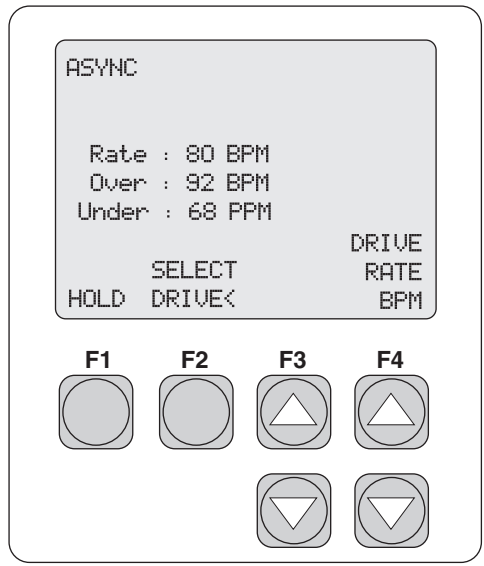
eyr032.eps

1. From the **SELECT TEST** menu, press **F3 ASYNC MODE**.



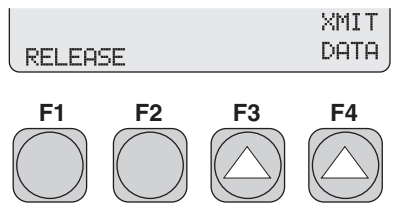
eyr068.eps

2. Press **F4 LOAD UP** or **DOWN** arrow key to select the load.
3. Press **F1 START** to advance the screen and start the test.



eyr040.eps

4. Press **F2 SELECT DRIVE<** to toggle between the Over and Under BPM rates.
5. Once a rate is selected use **F4 DRIVE RATE BPM UP** or **DOWN** arrow key to adjust that rate.
6. Press **F1 HOLD** to advance the screen:

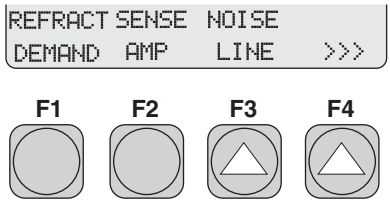


eyr016.eps

7. Press **F4 XMIT DATA** to transmit data through the serial port.
8. Press **F1 RELEASE** to release the hold and return to the **HOLD** screen.
9. Press **ESC** to return to previous menu(s).

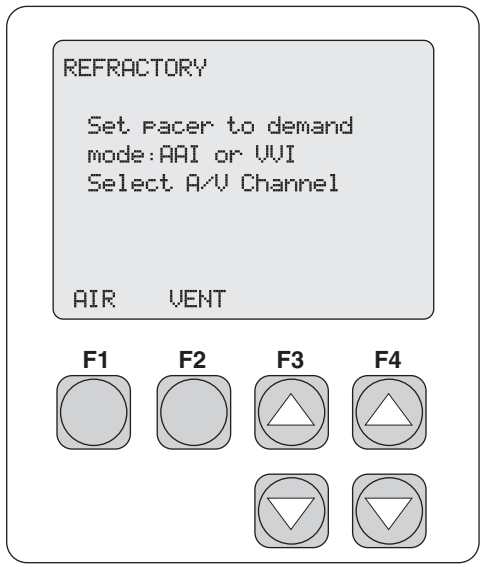
Demand Mode Pacemaker's Ability to Sense ECG Activity

The two following, related tests, PRP and SRP, determine the demand mode pacemaker's ability to sense ECG activity immediately following either a paced event (PRP) or a sensed ECG event (SRP).



eyr033.eps

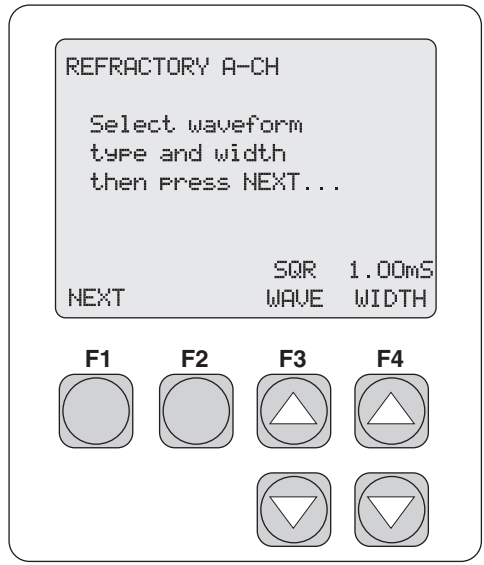
1. From the **SELECT TEST** menu, press **F1 REFRACT DEMAND**.



eyr069.eps

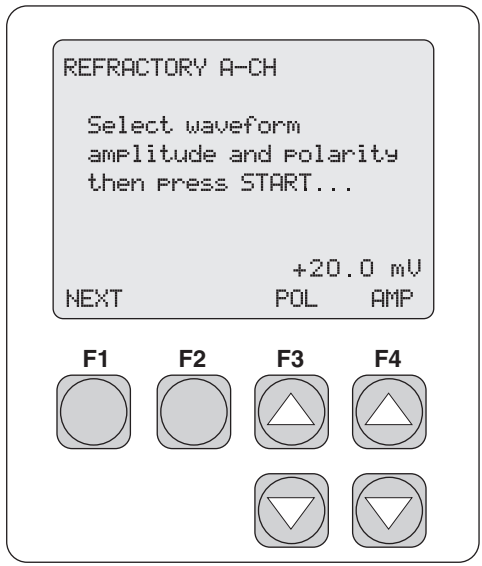
2. Select either of the two options:
   - **F1 ATR** for the atrial channel.
   - **F2 VENT** for the ventricular channel.

The screen advances for wave and width selection (the example is the atrial channel).



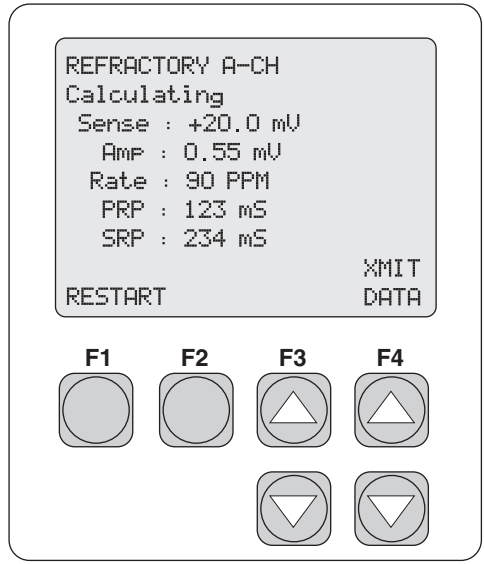
eyr070.eps

4. Press **F3 WAVE UP** or **DOWN** arrow key to select a waveform.
5. Press **F4 WIDTH UP** or **DOWN** arrow key to adjust the width of the waveform.
6. Press **F1** to advance to the next screen.



eyr071.eps

7. Press **F3 POLARITY UP** or **DOWN** arrow key to toggle the polarity.
8. Press **F4 AMPLITUDE** to adjust amplitude.
9. Press **F1 START** to advance the screen and start the test.

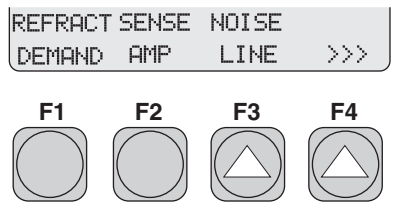


eyr042.eps

10. Press **F4 XMIT DATA** to transmit data.
11. Press **F1 RESTART** to restart the test.
12. Press **ESC** to return to previous menu(s).

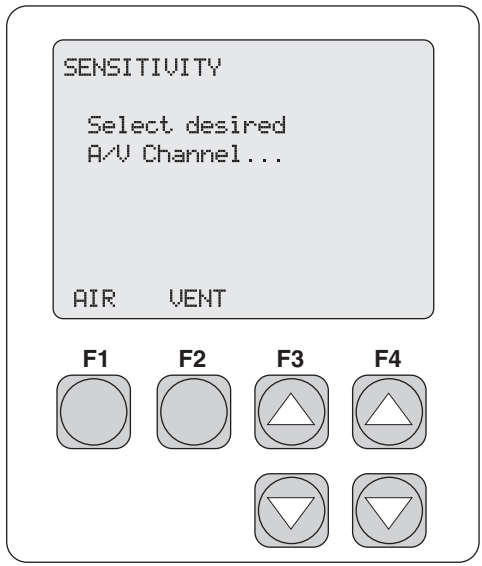
Amplitude of ECG Signal for a Demand Mode Pacemaker

This test determines the required amplitude of the simulated ECG signal to be detected by the demand mode pacemaker.



eyr033.eps

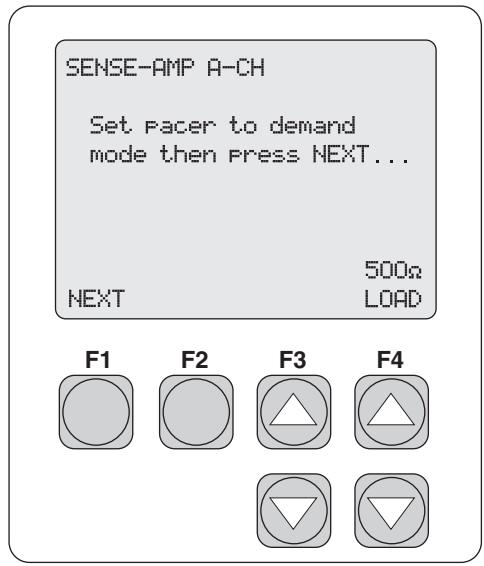
1. From the **SELECT TEST** menu, press **F2 SENSE AMP**.



eyr072.eps

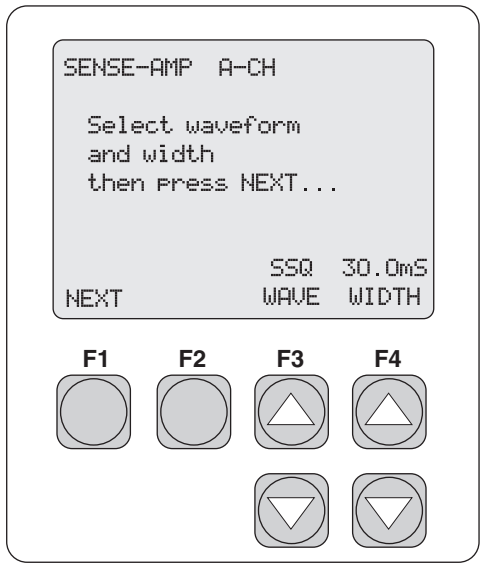
2. Select either of the two options:
   - **F1 ATR** for the atrial channel.
   - **F2 VENT** for the ventricular channel.

   After pressing the desired key, the appropriate screen appears:



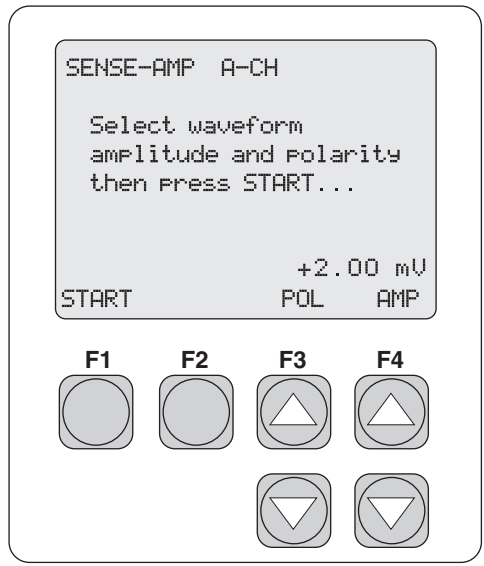
eyr073.eps

3. Press **F4 LOAD UP** or **DOWN** arrow key to select the load.
4. Press **F1 NEXT** to advance to the next screen.



eyr075.eps

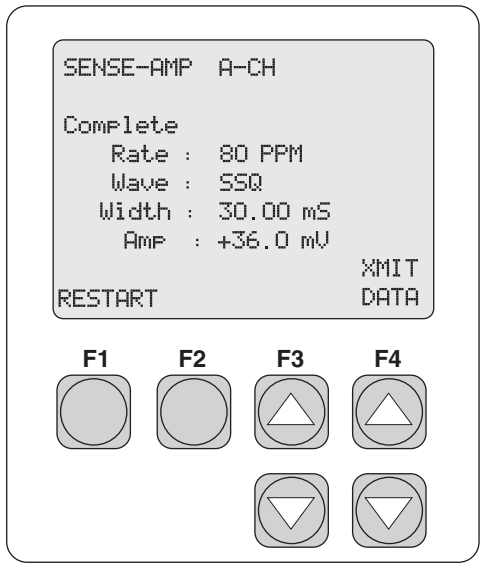
5. Press **F3 WAVE UP** or **DOWN** arrow key to select a waveform.
6. Press **F4 WIDTH UP** or **DOWN** arrow key to adjust the width of the waveform.
7. Press **F1 NEXT** to advance to the next screen.



eyr076.eps

8. Press **F3 POL UP** or **DOWN** arrow key to select polarity.
9. Press **F4 AMP UP** or **DOWN** arrow key to adjust amplitude.
10. Press **F1 START** to start the test and advance to the next screen.

    After calculations, the following screen appears.

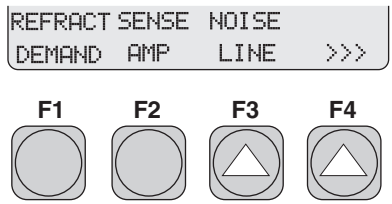


eyr077.eps

11. Press **F4 XMIT DATA** to transmit data.
12. Press **F1 RESTART** to restart the test.
13. Press **ESC** to return to previous menu(s).

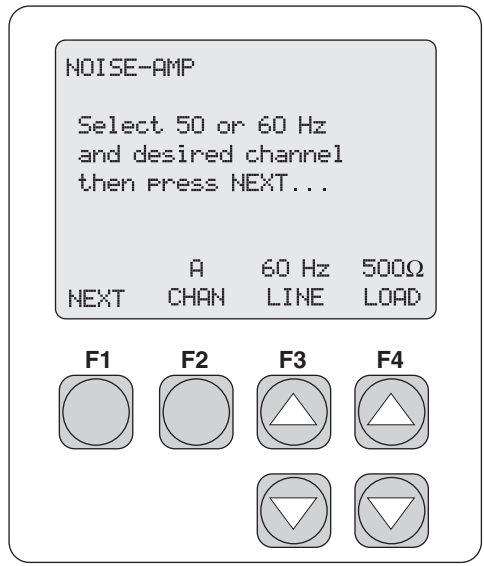
Pacemaker's Ability to Filter Line Noise

This test measures the pacemaker's ability to filter line noise at either 50 or 60 Hz.



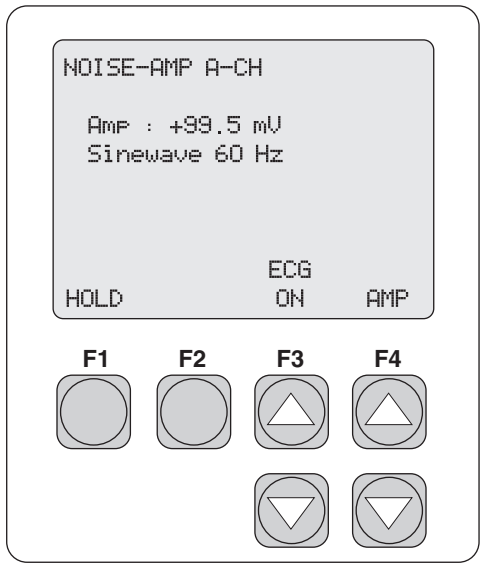
eyr033.eps

1. From the **SELECT TEST** menu, press **F3 NOISE LINE**.



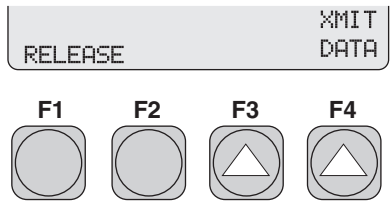
eyr078.eps

2. Press **F2 CHAN** to toggle between the two options:
   - **A** - atrial channel
   - **V** - **v**entricular channel.
3. Press **F3 LINE** to toggle between two line frequencies (50 or 60 Hz).
4. Press **F4 LOAD UP** or **DOWN** arrow key to select the load.
5. Press **F1 NEXT** to advance to the next screen.



eyr044.eps

6. Press **F3 ECG** to toggle the ECG function **ON** or **OFF**.
7. Press **F4 AMP UP** or **DOWN** arrow key to adjust the amplitude of the noise line frequency selection.
8. Press **F1 HOLD** to advance the screen:



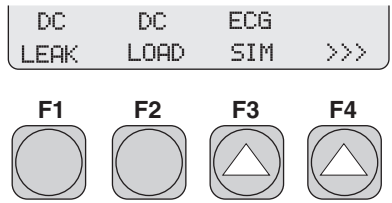
eyr016.eps

9. Press **F4 XMIT DATA** to transmit data through the serial port.
10. Press **F1 RELEASE** to release the hold and return to the **HOLD** screen.
11. Press ESC to return to previous menu(s).

Integrity of the Pacemaker's Final Stage

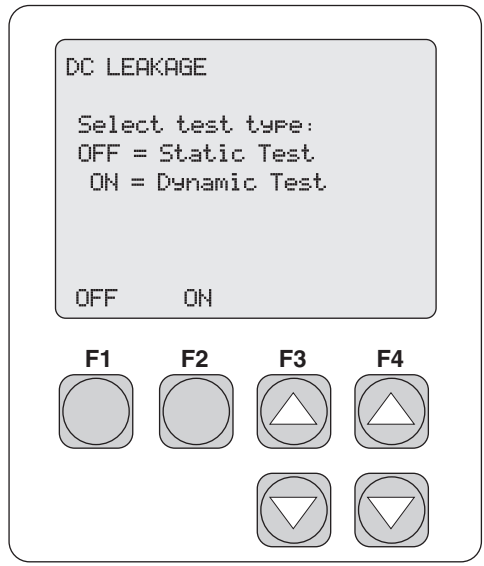
The integrity of the pacemaker's final stage is evaluated, using the following tests.

DC Leak Test



eyr034.eps

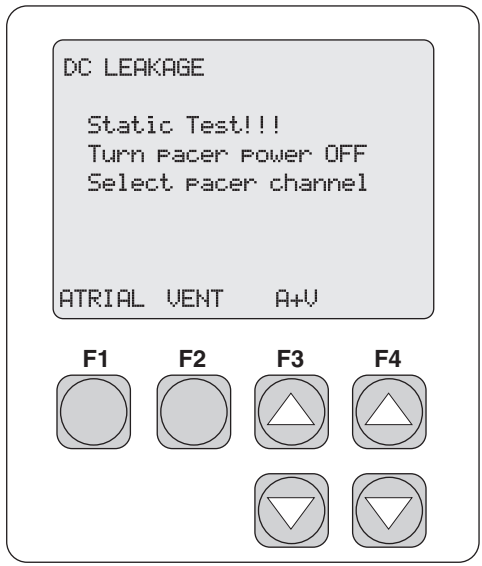
1. From the **SELECT TEST** menu, press **F1 DC LEAK**.



eyr080.eps

2. Select a test type:
   - **F1 OFF** - Static test (Turn pacemaker power OFF)
   - **F2 ON** - Dynamic test (Turn pacemaker power ON)

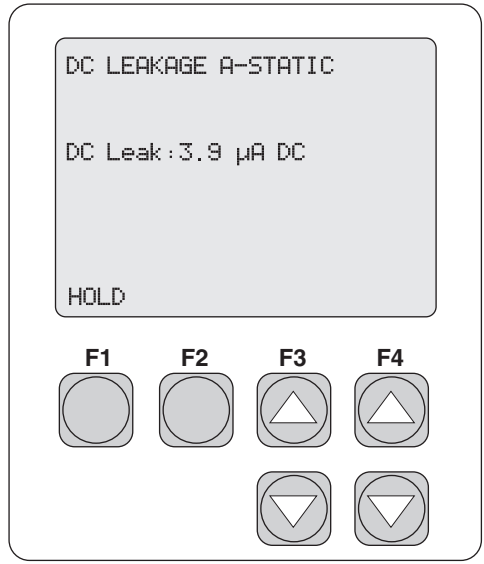
   The screen advances:



eyr081.eps

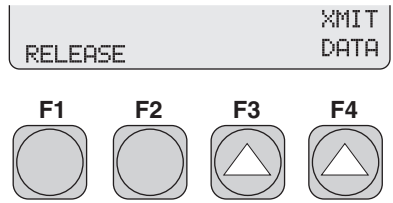
3. Press one of the three options:
   - **F1 ATRIAL** for atrial channel only
   - **F2 VENT** for ventricular channel only
   - **F3 A+V** for both atrial and ventricular channels

   The screen advances:



eyr046.eps

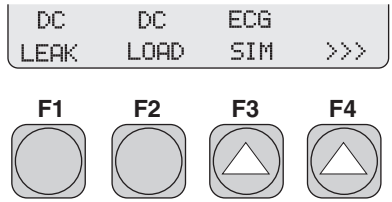
9. Press **F1 HOLD** to advance the screen:



eyr016.eps

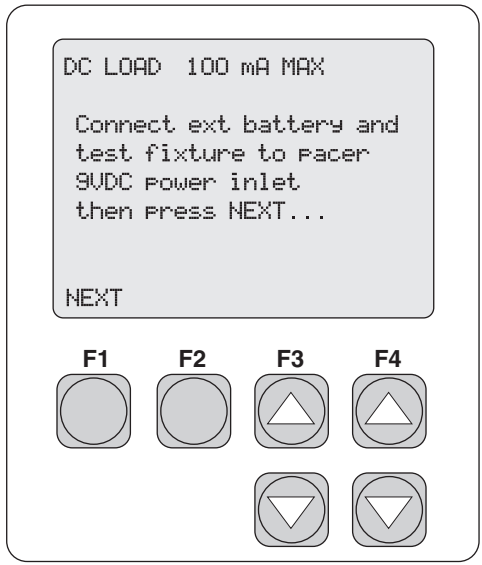
12. Press **F4 XMIT DATA** to transmit data through the serial port.
13. Press **F1 RELEASE** to release the hold and return to the **HOLD** screen.
14. Press **ESC** to return to previous menu(s).

DC Load Test



eyr034.eps

1. From the **SELECT TEST** menu, press **F2 DC LOAD**.



eyr083.eps

2. Make necessary connections, as follows:

   a. Plug the supplied 9 V dc Load Test Cable into the matching connector on the left side of the Analyzer.

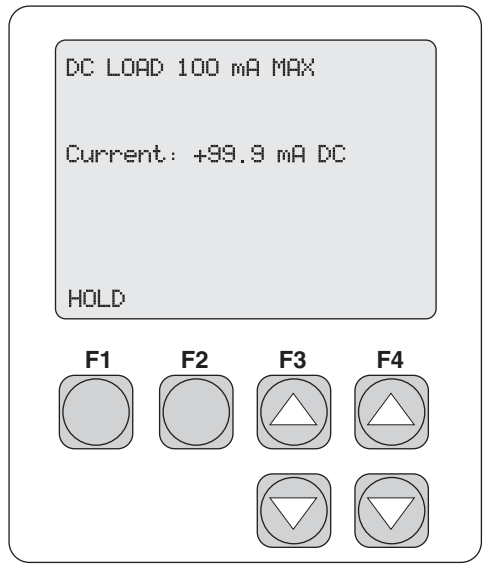
   b. A 9 V dc Load Test Cable (Fluke Biomedical Part# 2201074) is supplied as a standard accessory with the Analyzer. It is designed specifically for the testing of Medtronic models 5388 Dual Channel and 5348 Single Channel transvenous pacemakers.

c. Remove the battery from the pacemaker and slide the black block (with the two banana plugs) into the empty battery compartment.

d. Apply light pressure to the pacemaker's battery compartment door to seat the test fixture to the recessed battery terminals.

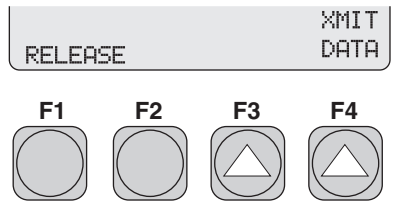
e. To test other brands and/or models of transvenous pacemakers, just attach test leads (not supplied) between the test fixture banana plugs and the exposed battery contacts.

3. Press **F1 NEXT** to advance the screen and start the test.



eyr047.eps

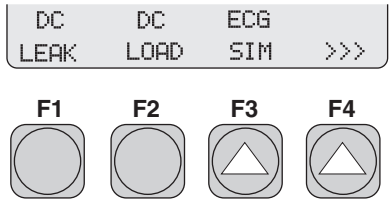
4. Press **F1 HOLD** to advance the screen:



eyr016.eps

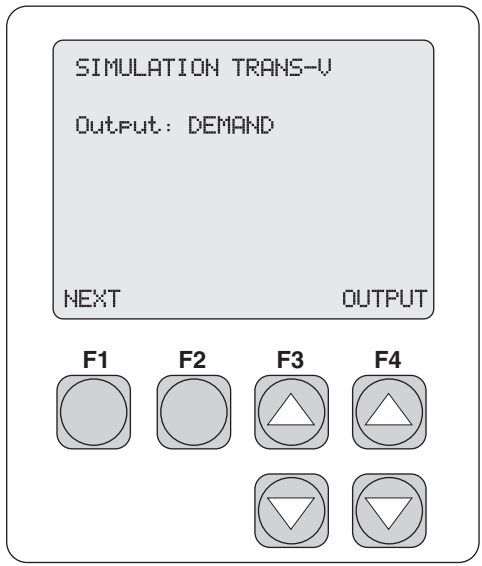
5. Press **F4 XMIT DATA** to transmit data through the serial port.
6. Press **F1 RELEASE** to release the hold and return to the **HOLD** screen.
7. Press **ESC** to return to previous menu(s).

ECG Simulation Test



eyr034.eps

1. From the **SELECT TEST** menu, press **F3 ECG SIM**.

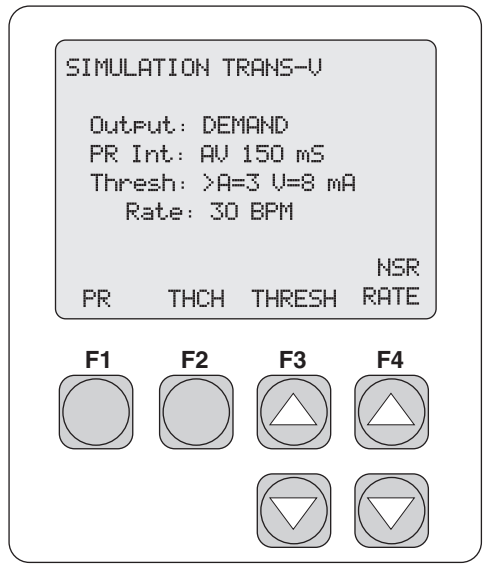


eyr085.eps

2. Press **F4 OUTPUT** to toggle among four simulated operational modes:
   - Demand
   - Continuous

- Non-Capture
- Non-Function

3. Press **F1 NEXT** to advance to the following screen:



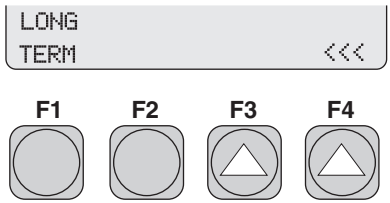
eyr048.eps

4. Press **F1 PR** to adjust the PR Interval.
5. Press **F2 THCH** to toggle between atrial and ventricular of the threshold amplitude.
6. Press **F3 THRESH UP** or **DOWN** arrow key to adjust the selected atrial or ventricular threshold amplitude.
7. Press **F4 NSR RATE UP** or **DOWN** arrow key to adjust the NSR rate of the simulation ECG signal.
8. Conduct pacemaker testing, using the Analyzer to provide the ECG signal.
9. Press **ESC** to return to previous menu(s).

Long Term Tests

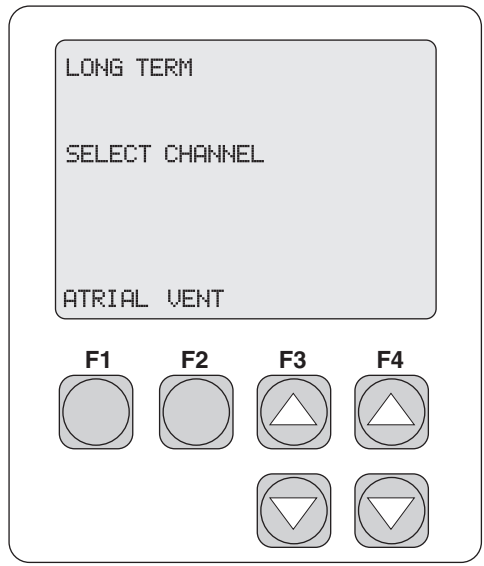
Tests are preformed for only one channel at a time. The overall stability of the pacemaker's pulse rate and amplitude are monitored continuously over an extended period of time. The user enters the desired target values for these two parameters into the Analyzer. This program flexibility allows the user to enter either the actual test pacemaker values or the selected rate and amplitude settings.

Deviation values are independently selectable from 2 % to 20 % in 1 % increments. The Analyzer compares these incoming pacer pulses to the target values. When the long-term test is complete, output pulses from the pacemaker that were not within the selected limits may be reviewed.



eyr035.eps

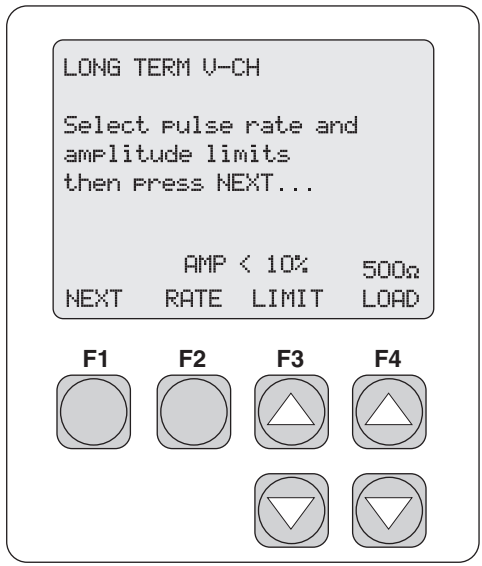
1. From the **SELECT TEST** menu, press **F3 LONG TERM**.



eyr049.eps

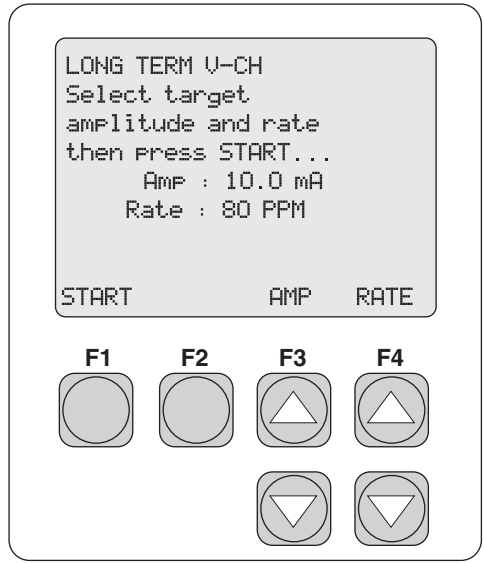
2. Select one of the following two options:
   - Press **F1 ATRIAL** for the atrial channel.
   - Press **F2 VENT** for the ventricular channel.

   The screen advances (the example is the ventricular channel):



eyr050.eps

3. Press **F2 RATE** to toggle between pulse rate and amplitude. This parameter works with the **LIMIT** parameter to assign limits to both.
4. For each, pulse rate and amplitude, press **F3 LIMIT UP** or **DOWN** arrow key to select the limit value.
5. Press **F4 LOAD UP** or **DOWN** arrow key to select the load.
6. Press **F1 NEXT** to advance to the next screen.

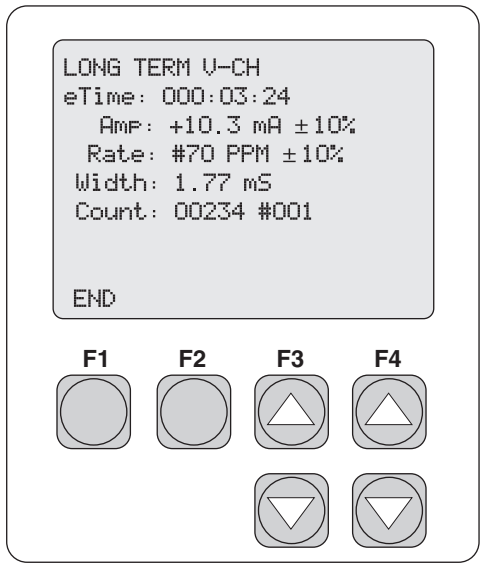


eyr051.eps

7. Press **F3 AMP** to adjust the amplitude.
8. Press **F4 RATE** to adjust the rate.
9. Press **F1 START** to advance screen and start the test.

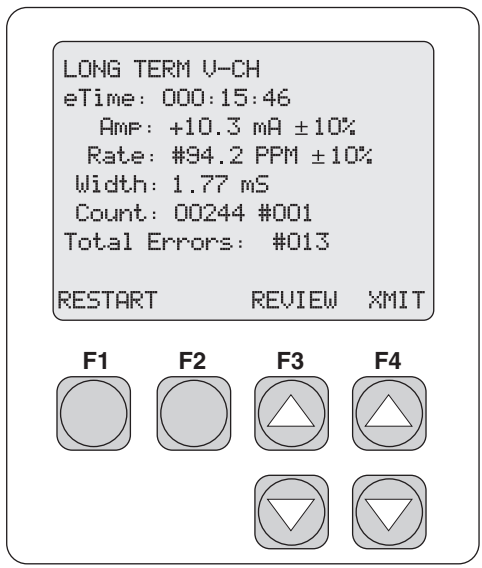
Note

Target values for amplitude and rate must be entered for test to perform correctly.



eyr052.eps

10. Press **F1 END** to end the test.



eyr053.eps

11. Press **F3 REVIEW UP** or **DOWN** arrow key to view deviations falling outside the selected deviation values for rate and amplitude.

    Up to 200 deviations are stored in the Analyzer memory. Any long term test exceeding 200 deviations is automatically terminated. The pulse width at the "out of limit" pacemaker pulse is also reported.

12. Press **F4 XMIT** to transmit data.
13. Press **F1 RESTART** to restart the test.
14. Press **ESC** to return to previous menu(s).

Chapter 5
Remote Operation

Contents **Page**

Introduction 5-3
Entering Remote Mode 5-3
Working in Remote Mode 5-3
Exiting Remote Mode 5-3
Command Syntax 5-4
Responses to Commands 5-4
Remote Mode Analyzer Setup Commands 5-4
Error Codes 5-5
Transcutaneous Pacemaker Remote Setup and Testing 5-6
Transvenous Pacemaker Remote Setup and Testing 5-13

Introduction

Remote commands can be used to control the Analyzer. Remote operations can be accessed through the RS232 serial port, using a controller, such as the medTester 5000C or a personal computer. The remote mode of operation provides Analyzer command/control and data capture/transfer functions.

Primary commands are valid when the instrument is in the MAIN MENU or in the REMOTE MAIN mode.

At power up, global variables are set to the default. The global variable setup commands are valid in the MAIN MENU and also in the modes where they are listed. If power is interrupted and restores, the Analyzer powers up in the manual mode.

Entering Remote Mode

When a valid REMOTE command is received from the MAIN MENU, the instrument enters the REMOTE MAIN mode. This remote mode cannot be entered directly from the sleep mode. The local (manual) user interface is inactive and unavailable during remote operation.

When entering a transcutaneous or transvenous pacemaker mode, the variables for that mode are set to the default. The default setting is the one listed first, unless otherwise stated. Other measurement commands are valid only in the specific mode they are listed in.

Working in Remote Mode

See “Transcutaneous Pacemaker Remote Setup and Testing” and “Transvenous Pacemaker Remote Setup and Testing”, below, for pacemaker-specific commands associated with remote operation.

To exit any remote mode test, sent the EXITTEST command, returning to the REMOTE MAIN MODE.

Exiting Remote Mode

To exit the remote mode, send the LOCAL command; returning the instrument to the MAIN MENU and local control.

Command Syntax

Commands can be sent in upper or lower case. All command strings must be terminated with a carriage return [CR] and/or a line feed [LF] in the format [command][CR][LF]. Spaces are ignored.

A command shown with an equals sign (=) is a setup command that requires at least one parameter to be included with the command. Multiple parameters are separated by commas. All possible parameter choices are shown. Unless otherwise stated, the default parameters are listed first.

Responses to Commands

The instrument responds to all commands. Commands that do not return any other message or data return the confirmation, OK. After receiving a command, the instrument ignores all other incoming characters until it has responded to the one at hand.

Remote Mode Analyzer Setup Commands

The following are common commands associated with setting up remote operation of the Analyzer.

VER.XX

The firmware version level is returned in a three-digit format with a fixed decimal point. (Example: VER = 1.03)

Beta version firmware is identified with an additional pair of alphanumeric characters (Example: VER= 1.03B1)

IDENT

The firmware returns the identity of the Analyzer name and firmware revision (Example: IDENT= ANALYZER 1.03)

REMOTE

The Analyzer enters the remote mode of operation.

All serial commands that do not return data or a predetermined response send OK to indicate that the serial command was received, understood and executed.

LOCAL

The Analyzer enters the local (manual) mode of operation.

QBAUD

Diagnostic; the baud rate setting of the Analyzer is transmitted to the host controller in response to this serial command.

BAUD=nnnn (Only baud rate settings of 2400, 9600, or 19200 are valid).

Error Codes

The following error codes are returned in response to commands that cannot be executed.

ERR=00

No commands allowed at this time

ERR=01

Unknown command

(Returns the question mark character (?) to the host controller via the serial port.)

ERR=02

Illegal command. The command was recognized, but not allowed at this time

ERR=03

Illegal parameter. A parameter sent as part of the command was not the correct type or was out of range; or, it contained an incorrect number of parameters.

Transcutaneous Pacemaker Remote Setup and Testing

The following commands are associated with setting up and testing a transcutaneous pacemaker in remote mode.

SETMODE

SETMODE=TQPACE

Selects the Analyzer's transcutaneous pacer test mode of operation.

Note

All subsequent serial port communications must relate to transcutaneous pacer features and follow the prescribed measurement protocols listed below.

SETMAKE

SETMAKE=nnnn

The specific protocol required for each manufacturer (or make) is selected using this command. Each protocol contains a set of measurement algorithms for rate, width, amplitude, and refractory. SETMAKE= followed by the four-digit alphanumeric entry assigned to each manufacturer completes this serial command.

The following table shows the SETMAKE protocol for the indicated manufacturers (Example: SETMAKE = ZM07).

Table 5-1. SETMAKE Protocols by Manufacturer

Manufacturer (Make)	Selection
Default/Physio-Control/Cardiotronics	PC01
Hewlett Packard Codemaster	HP02
Marquette Medical	MQ03
Medical Data Electronics	MD04
Medical Research Laboratories	MR05
Zoll Medical PD1200 – 2000	ZP06
Zoll Medical M-Series	ZM07

RDMAKE

This command returns the NAME and Reference # for the specified make. (Example: ZM-07 = Zoll Medical M-Series pacemaker)

SETLOAD

SETLOAD=nnnn

This command is used to select the desired test load. The above “nnnn” represents the actual test load resistance value (in ohms) and is based upon the available factory preset selections.

(Example: SETLOAD=0050 is the command for a 50 Ω test load)

Selections for "nnnn" range from 0050 to 1550, in 50 Ω increments.

RDLOAD

Reads the current test load setting. When this command is sent to the Analyzer it returns: LOAD=nnnn; where nnnn equals the resistance in ohms from 50 to 1550 Ω.

SETTEST

SETTEST=PULSE

The Analyzer monitors the applied pulse rate, amplitude, width, and energy data.

HOLD

Freezes the pacer measurement and maintains the last reading in memory.

RDMETER

The Analyzer transmits the following information string for rate, amplitude and width from the data "frozen" from the above HOLD serial command.

The data is returned in the following vertical format: AMP=XXX mA, RATE=XXX PPM, WIDTH=XXX mS. For each parameter, the Analyzer returns a three-digit numeric value (XXX) with a floating decimal point to cover the multiple ranges. The unit of measure remains the same for all transmitted readings (mA, PPM and mS). Additionally, single parameter information can be acquired.

RDMETERH

The data is returned in the following horizontal format:

AMP=XXX mA, RATE=XXX PPM.

RDAMP

The Analyzer transmits the following information string for amplitude from the data "frozen" with the above HOLD serial command. The data is returned in the following format: AMP=XXXmA

RDRATE

The Analyzer transmits the following information string for rate from the data "frozen" with the above HOLD serial command. The data is returned in the following format: RATE=XXXPPM

RDWIDTH

The Analyzer transmits the following information string for width from the data "frozen" with the above HOLD serial command. The data is returned in the following format: WIDTH=XXXmS

RDENERGY

Even though the pacemaker pulse energy reading is not displayed when the RDMETER serial command is utilized, it is computed. The Analyzer transmits information from the data "frozen" with the HOLD serial command.

One of the following formats is used, depending on the energy level of the transcutaneous pacemaker pulse.

ENERGY= XXX?J

ENERGY=XXXmJ

ENERGY=X.XXJ

RESUME

Releases the HOLD serial command and proceeds with making measurements.

SETTEST=DEMAND

The Analyzer enters the qualitative demand test. The applied pacemaker pulse rate is measured; if it is ZERO, the Analyzer transmits RATE=000 and will not

start the test until a pulse rate is detected. If the rate is between 30 and 200 PPM it waits for either of the following commands:

OVERDRIVE=nn

The Analyzer computes an overdrive (higher) ECG signal rate based upon the earlier measured pacemaker pulse rate. A two-digit number (nn) represents the percentage that ECG signal is higher than the measured pacemaker pulse rate. (Example: With a measured pacemaker pulse rate of 60 PPM and the following overdrive command

OVERDRIVE=20, a computed ECG signal rate of 72 BPM is generated.) The pacemaker will either PASS or FAIL this qualitative test based upon the criteria stated in the main product specification document.

UNDERDRIVE=nn

The Analyzer computes an underdrive (lower) ECG signal rate based upon the earlier measured pacemaker pulse rate. A two-digit number (nn) represents the percentage that ECG signal is lower than the measured pacemaker pulse rate. (Example: With a measured pacemaker pulse rate of 60 PPM and the following underdrive command of UNDERDRIVE=20, a computed ECG signal rate of 48 BPM is generated.) The pacemaker will either PASS or FAIL this qualitative test based upon the criteria stated in the main product specification document.

SETTEST=ASYNC

The Analyzer begins the async test by measuring the pacemaker pulse rate; if it is ZERO, the Analyzer transmits RATE=000 and will not start the test until a pulse rate is detected.

OVERDRIVE=nn

The Analyzer computes an overdrive (higher) ECG signal rate based upon the earlier measured pacemaker pulse rate. A two-digit number (nn) represents the percentage that ECG signal is higher than the measured pacemaker pulse rate. (Example: With a measured pacemaker pulse rate of 60 PPM and the following overdrive command of OVERDRIVE=20, a computed ECG signal rate of 72 BPM is generated.) The pacemaker will either PASS or FAIL this

qualitative test based upon the criteria stated in the main product specification document.

UNDERDRIVE=nn

The Analyzer computes an underdrive (lower) ECG signal rate based upon the earlier measured pacemaker pulse rate. A two-digit number (nn) represents the percentage that ECG signal is lower than the measured pacemaker pulse rate. (Example: With a measured pacemaker pulse rate of 60 PPM and the following underdrive command of UNDERDRIVE=20, a computed ECG signal rate of 48 BPM is generated.) The pacemaker will either PASS or FAIL this qualitative test based upon the criteria stated in the main product specification document.

SETTEST=RFRACT

The Analyzer begins the refractory test by measuring the pacemaker pulse rate; if it is ZERO, the Analyzer transmits RATE=000 and will not start the test until a pulse rate is detected. The paced refractory period is first computed and then reported in the following format: PRP=XXX mS. The sensed refractory period (SRP) is computed and reported in the following format: SRP=XXX mS.

Note

This reported data has three-digits and no displayed decimal point.

SETTEST=SENSE

The demand sensitivity test can run with one of three different waveforms: square, triangle, and sine-squared. Set the test to SENSE, then select the desired waveform for the test.

SENSE=SQU, nnn.nn

SENSE=TRI, nnn.nn

SENSE=SSQ, nnn.nn

SENSE=HSN, nnn.nn

The “nnn” represents the width selection (mS) of the sensitivity test waveform.

The Analyzer begins the demand sensitivity test by measuring the pacemaker pulse rate; then it places the selected waveform at 50 % of the pacemaker pulse-to-pulse rate interval and initiates the protocol as stated in the main product specification document.

The Analyzer response displays:

SENSE=XXX,ZZZ.ZZm,SYYYmV.

XXX is the waveform type, as indicated above.

ZZZ.ZZ is the pulse width.

YYY are the three-digit amplitude numeric reading, either with or without the floating decimal point.

(Example: SENSE=SSQ,100mS,12.5mV for the sine-square selection @ 12.5 mV amplitude and width of 100 mS.)

SETTEST=NOISE

The Analyzer generates a sine wave at the power line frequency of either 50 or 60 Hz at a prescribed amplitude (Range: 0 to 10.0 mV in 0.50 mV steps) upon the receipt of this command. Both the frequency and the amplitude of this sine wave are encrypted in the following serial command structure.

The serial command structure is: NOISE=XX,nn.n where the XX represents the power line frequency in Hz (50 or 60) and nn.n represents the amplitude in millivolts. Example: NOISE=60,05.5 generates a sine wave at a frequency of 60 Hz at an amplitude of 5.5 mV.

ECG= ON

ECO=OFF

SETTEST=TREND

The Analyzer runs the prescribed trend test using 02 % to 20 % as the deviation point from the computed average pulse amplitude, rate, and width.

TREND=uu,nnnn,zz,nnn

uu= % test limit for amplitude.

nnnn= Set point for amplitude (0.1 mA resolution.)

zz= % test limit for rate.

nnn= Set point for rate (1PPM resolution.)

The data is returned in the following format;

AMP=#XXX mA, RATE=#XXX PPM, WIDTH=XXX mS when a reading is out of the prescribed test limit range. For each parameter, the Analyzer returns a three-digit numeric value (XXX) with a floating decimal point to cover the multiple ranges. The unit of measure remains the same for all transmitted readings (mA, PPM, and mS). The Analyzer marks the out-of-limit readings with the pound (#) sign.

TRENDEND

Halts the trend test.

EXITTEST

Leaves the selected test measurement.

EXITMODE

Halts all tests and returns the Analyzer to the main serial control menu.

Transvenous Pacemaker Remote Setup and Testing

The following commands are associated with setting up and testing a transvenous pacemaker in remote mode.

The synchronized measurement of the pacemaker's atrial and ventricular output (amplitude, rate, width, energy activity) can be easily accomplished using the Analyzer in a dual-channel mode. The remaining pacemaker tests (demand, async, sensitivity, trend) or the setting of specific adjustments (test load) must be conducted for only one channel at a time.

SETMODE

SETMODE=TVPACEA (atrial channel only)

SETMODE=TVPACEV (ventricular channel only)

SETMODE=TVPACEAV (Both atrial and ventricular channels)

Selects the Analyzer's transvenous pacer test mode of operation.

Note

All subsequent serial port communications must relate to transvenous pacer features and follow the prescribed measurement protocols listed below.

SETLOAD

SETLOAD=nnnn (Both atrial and ventricular channels)

This command is used to select the desired test load. The above "nnnn" represents the actual test load resistance value (in ohms) and is based upon the available factory preset selections. The default test load value is 500 Ω for both channels.

(Example: SETLOAD=0500 is the command for the selection of a 500 ohm test load for both the atrial and ventricular channels.)

Valid selections for "nnnn" are as follows: 0200, 0500, and 1000 Ω

RDLOAD

Reads the current test load setting. When this command is sent to the Analyzer, it returns nnnn; where nnnn equals resistance in ohms from 0200 to 1000 Ω.

SETTEST

SETTEST=PULSE

The Analyzer monitors the applied pulse rate, amplitude, width, and energy data for both the atrial and the ventricular pacemaker channels.

HOLD

Freezes the pacer measurement and maintains last reading in memory for both the atrial and the ventricular pacemaker channels.

RDA
RDV

The Analyzer transmits the following information for rate, amplitude, and width from the atrial or the ventricular data "frozen" from the above HOLD serial command. The data is returned in the following format:

AMP=XXX mA

RATE=XXX PPM

WIDTH=XXX mS

For each parameter, the Analyzer returns a three-digit numeric value (XXX) with a floating point decimal to cover the multiple ranges. The unit of measure remains the same for all transmitted readings (mA, PPM, and mS).

RDAH

Returns atrial amplitude and rate.

RDVH

Returns ventricular amplitude and rate.

RDAV

The Analyzer transmits the following information string for rate, amplitude, and width from the atrial or the ventricular data "frozen" from the above HOLD serial command.

The data is returned in the following format:

A Channel: AMP=XXX mA, RATE=XXX PPM, WIDTH=XXX mS

V Channel: AMP=XXX mA, RATE=XXX PPM, WIDTH=XXX mS

AV Interval: XXX mS

For each parameter, the Analyzer returns a three-digit numeric value (XXX) with a floating point decimal to cover the multiple ranges. The unit of measure remains the same for all transmitted readings (mA, PPM and mS)

RDMETERAVI

This command is compatible with dual-chamber AV sequential pacemakers only. The Analyzer transmits the following information string for the AV interval (or delay) from the atrial and the ventricular data "frozen" from the above HOLD serial command.

The data is returned in the following format:

AV Interval: XXX mS

The Analyzer returns a three-digit numeric value (XXX) with a floating point decimal to cover the multiple ranges. The unit of measure remains the same for all transmitted readings (mS)

Additionally, single parameter information can be acquired for either of the channels:

RDAMPA
RDAMPV

The Analyzer transmits the following information string for amplitude from the data "frozen" with the above HOLD serial command.

The data is returned in the following format:

A Channel: AMP=XXXmA

V Channel: AMP=XXXmA

For each parameter, the Analyzer returns a three-digit numeric value (XXX) with a floating point decimal to cover the multiple ranges. The unit of measure remains the same for all transmitted readings (mA)

RDRATEA
RDRATEV

The Analyzer transmits the following information string for rate from the data "frozen" with the above HOLD serial command.

The data is returned in the following format:

A Channel: RATE=XXXPPM

V Channel: RATE=XXXPPM

RDWIDTHA
RDWIDTHV

The Analyzer transmits the following information string for width from the data "frozen" with the above HOLD serial command.

The data is returned in the following format:

A Channel: WIDTH=XXXmS

V Channel: WIDTH=XXXmS

RDENERGYA
RDENERGYV

A pacemaker pulse energy reading is not displayed when the above RDMETER serial command is evoked. It is computed and the Analyzer transmits the following information from the data "frozen" from the above HOLD serial command in one of these formats depending upon the energy level of the transvenous pacemaker pulse.

A Channel: ENERGY= XXXnJ,

ENERGY=XXXµJ

V Channel: ENERGY= XXXnJ,

ENERGY=XXXµJ

RESUME

Releases the HOLD serial command and proceeds to making measurements.

SETTEST=DEMAND

The Analyzer enters the qualitative demand test. All serial commands that do not return data or a predetermined response send OK to indicate that the serial command was received, understood, and executed. The applied pacemaker pulse rate is measured; if it is ZERO, the Analyzer shall transmit RATE=000 and not start the test until a pulse rate is detected. If the rate is between 30 and 200 PPM it waits for either of the following commands:

OVERDRIVE=nn

The Analyzer computes a dual (AV) channel overdrive (higher) ECG signal rate based upon the earlier measured pacemaker pulse rate. A two-digit number (nn) represents the percentage that ECG signal is higher than the measured pacemaker pulse rate. (Example: With a measured pacemaker pulse rate of 60 PPM and the following overdrive command of OVERDRIVE=20, a computed ECG signal rate of 72 BPM is generated.)

All serial commands that do not return data or a predetermined response send OK to indicate that the serial command was received, understood and executed. The pacemaker will either PASS or FAIL this qualitative test based upon the criteria stated in the main product specification document.

UNDERDRIVE=nn

The Analyzer computes a dual (AV) channel underdrive (lower) ECG signal rate based upon the earlier measured pacemaker pulse rate. A two-digit number (nn) represents the percentage that ECG signal is lower than the measured pacemaker pulse rate. (Example: With a measured pacemaker pulse rate of 60 PPM and the following underdrive command of UNDERDRIVE=20, a computed ECG signal rate of 48 BPM is generated.)

All serial commands that do not return data or a predetermined response shall send OK to indicate that the serial command was received, understood and executed. The pacemaker will either PASS or FAIL this qualitative test based upon the criteria stated in the main product specification document.

SETTEST=ASYNC

The Analyzer begins this async test by measuring the pacemaker pulse rate; if it is ZERO, the Analyzer transmits RATE=000 and will not start the test until a pulse rate is detected.

OVERDRIVE=nn

The Analyzer computes a dual (AV) channel overdrive (higher) ECG signal rate based upon the earlier measured pacemaker pulse rate. A two-digit number (nn) represents the percentage that ECG signal is higher than the measured pacemaker pulse rate. (Example: With a measured pacemaker pulse rate of 60 PPM and the following overdrive command of OVERDRIVE=20, a computed ECG signal rate of 72 BPM is generated.) The pacemaker will either PASS or FAIL this qualitative test based upon the criteria stated in the main product specification document.

UNDERDRIVE=nn

The Analyzer computes a dual (AV) channel underdrive (lower) ECG signal rate based upon the earlier measured pacemaker pulse rate. A two-digit number (nn) represents the percentage that ECG signal is lower than the measured pacemaker pulse rate. (Example: With a measured pacemaker pulse rate of 60 PPM and the following underdrive command of UNDERDRIVE=20, a computed ECG signal rate of 48 BPM is generated.) The pacemaker will either PASS or FAIL this qualitative test based upon the criteria stated in the main product specification document.

SETTEST=RFRACTA
SETTEST=RFRACTV

REFRACT=zzz,nnn.nn,nnn

zzz= SQU,TRI,SSQ,HSN

nnn.nn= Width in mS

nnn= Amplitude in mV

The Analyzer begins the refractory test by measuring the pacemaker pulse rate; if it is ZERO, the Analyzer transmits RATE=000 and will not start the test until a pulse rate is detected. The paced refractory period is computed, then reported in the following format: PRP=XXX mS. The sensed refractory period (SRP) is computed and reported in the following format: SRP=XXX mS. Note

Note

This reported data has three-digits and no displayed decimal point. It returns A=PRP=248mSRP=253mS.

SETTEST=SENSEA
SETTEST=SENSEV

The single-channel demand sensitivity test can run either on the atrial or the ventricular channels with one of three different waveforms: square, triangle and sine-squared at one of six pulse widths. Set the test to SENSE, then select the desired waveform for the test, and finally set the pulse width.

SENSE=SQU, nnn.nn

SENSE=TRI, nnn.nn

SENSE=SSQ, nnn.nn

SENSE=HSN, nnn.nn

The “nnn” represents the width selection (mS) of the sensitivity test waveform. Valid width entries are 010, 025, 030, 040, 100 and 200 mS only.

The Analyzer begins the demand sensitivity test by measuring the pacemaker pulse rate; then it places the selected waveform at 50 % of the pacemaker pulse-to-pulse rate interval and initiates the protocol as stated in the main product specification document. The Analyzer displays the following:

A Channel: SENSE=XXXZZZmSYYYmV

V Channel: SENSE=XXXZZZmSYYYmV

The XXX is the waveform type as indicated above.

ZZZ is the pulse width.

YYY is the three-digit amplitude numeric reading (either with or without the floating decimal point).

(Example: SENSE=SSQ100mS12.5mV for the sine-square selection @ 12.5 mV amplitude and width of 100 mS)

SETTEST=NOISEA (Atrial channel only)
SETTEST=NOISEV (Ventricular channel only)

The Analyzer generates a sine wave at the power line frequency of either 50 or 60 Hz at a prescribed amplitude (Range: 0 to 100 mV in 5 mV steps) upon the receipt of this command. This sine wave can be applied to a single channel (either atrial or ventricular). Both the frequency and the amplitude of this sine wave are encrypted in the following serial command structure.

The serial command structure is: NOISE=XX, nnn where the XX represents the power line frequency in Hz (50 or 60) and nn.n represents the amplitude in millivolts. Example: NOISE=60,055 generates a sine wave at a frequency of 60 Hz at an amplitude of 55 mV.

SETTEST=TREND

The Analyzer runs the prescribed trend test using 02 % to 20 % as the deviation point percentage from the selected pulse amplitude, and rate.

TREND=uu,nnnn,zz,www

uu= % test limit for amplitude.

nnnn= Set point for amplitude (0.1 mA resolution.)

zz= % test limit for rate.

nnn= Set point for rate (1 PPM resolution.)

The data is returned in the following format when a reading is out of the prescribed test limit range. For each parameter, the Analyzer returns a three-digit numeric value (XXX) with a floating decimal point to cover the multiple ranges. The unit of measure remains the same for all transmitted readings (mA, PPM and mS). The Analyzer marks out-of-limit readings with the pound (#) sign.

A Channel: AMP=#XXX mA, RATE=#XXX PPM, WIDTH=XXX mS

TRENDEND

Halts the trend test.

EXITTEST

Leaves the selected test.

SETTEST=DCLEAK

The basic dc leakage measurement function is activated when this serial command is received by the Analyzer. The following complementary serial commands are then used to select the specific measurement type and the input configuration of the Analyzer's dc micro-amp meter function.

DCLEAK=STATICA	Continuous measurement on the atrial inputs.
DCLEAK=STATICV	Continuous measurement on the vent inputs.
DCLEAK=STATICAV	Continuous measurement on the AV (+) inputs.
DCLEAK=DYNAMICA	Gated measurement on the atrial inputs.
DCLEAK=DYNAMICV	Gated measurement on the vent inputs.
DCLEAK= DYNAMICAV	Gated measurement on the AV (+) inputs.

RDDCLEAK

This command queries the Analyzer for the currently active dc leakage test reading and the Analyzer returns the data in the following format:

DCLEAK=+XX.X A.

Error Messages

Error messages are returned instead of data if the required test conditions are not fulfilled.

- During STATIC tests, an error message PULSE is returned if a pacer pulse output is present on the Analyzer input terminals during this "power off" continuous test.
- During the atrial and the ventricular channel DYNAMIC tests:

  An error message PULSE is returned if pulse output is present on the Analyzer input terminals during these "power on" triggered tests. This error message is not active during the DCLEAK=DYNAMICAV test since no discernable pulse should be present across the two A (+) and V (+) pacemaker channel outputs during the DDD mode of operation.

  An error message NO PULSE is returned if no pacer pulse output is present on the Analyzer input terminals during these two "power on" triggered tests. This error message is not active during the DCLEAK=DYNAMICAV test, since no discernable pulse should be present across the two A (+) and V (+) pacemaker channel outputs during the DDD mode of operation.

SETTEST=DCLOADI

The Analyzer measures the dc current present at its associated input terminals. This dc current can be input in either a positive (+) or negative (-) polarity.

RDDCLOADI

This command queries the Analyzer for the current dc load current test reading and the Analyzer returns the data in the following format:

DCLOADI=+XX.X mA

The polarity of the dc current is indicated with either positive (+) or negative (-) sign.

Readings are available in milliamperes as specified, if the input dc current exceeds the maximum response of: DCLOADI= XXX mA to the host controller.

EXITTEST

Exits the selected test measurement.

EXITMODE

Halts all tests and returns the Analyzer to main menu serial control.